Panadol Forte Suspension

- For over 50 years, Children's Panadol has given parents the confidence to get their kids back to being kids fast, through effective pain and fever relief. With Children's Panadol you can rest assured that nothing starts working faster than Paracetamol, the active ingredient in Panadol Forte Suspension.

Overview

- **What does it relieve?**
  Fever
  Mild to moderate pain associated with:
  - Toothache
  - Headache
  - Sore throat
  - Vaccination
  - Common Childhood Ear Infections

- **Dosage form**
  Available in suspension form

- **What are its features?**
  Pineapple Flavour
  Gentle on tiny tummies when used as directed

- **Composition**
  Each 5ml contains: Paracetamol 250 mg

How to Use

For oral administration only. Always read the label before use.

Dosage

- Minimum dosing interval: 4 hours
- Children aged 1 month and above.
- Maximum daily dosage: 60 mg/kg presented in divided in divided doses of 10-15 mg throughout the 24-hour period.
- No more than four doses in any 24-hour period
- Maximum duration of continued use without medical advice 3 days

Warnings and Precautions:

- Contains Paracetamol. Do not use with any other paracetamol-containing products. The concomitant products. The concomitant use with other products containing paracetamol may lead to an overdose.
- Paracetamol overdose may cause liver failure which can lead to liver transplant or death.
- Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.
- Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index or are chronic heavy users of alcohol or have sepsis.
- In patients with glutathione depleted states, the use of paracetamol may increase the metabolic acidosis.
- If symptoms persist, medical advice must be sought.

- Keep out of sight and reach of children.

Overdose:

- Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and peak after 4 to 6 days.

- Overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Treatment

- Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

- If overdose is confirmed or suspected, seek immediate advice from your Poison Centre or refer patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.

- Where a Poison Information Centre is not available, refer patient to the nearest Emergency Medical Centre for management and expert treatment.

- Administration of N-acetylcysteine or methionine may be required.

Drug Interactions

- The anticoagulant effect of warfarin and other coumarins may be prolonged regular daily use of paracetamol with increased risk of occasional doses have no significant effect.

Contraindications

- This product is contraindicated in patients with a previous history of hypersensitivity to paracetamol or excipients.

Adverse Reactions

- Thrombocytopaenia, Anaphylaxis cutaneous hypersensitivity reactions including among other skin rashes, angioedema Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm in patients sensitive to aspirin and other NSAIDS, hepatic dysfunction.

Panadol Liquid

- For over 50 years, Children's Panadol has given parents the confidence to get their kids back to being kids fast, through effective pain and fever relief. With Children's Panadol you can rest assured that nothing starts working faster than Paracetamol, the active ingredient in Panadol Forte Suspension.

Overview

- **What does it relieve?**
  Fever
  Mild to moderate pain associated with:
  - Toothache
  - Headache
  - Sore throat
  - Vaccination
  - Common Childhood Ear Infections

- **Dosage form**
  Available in liquid form

- **What are its features?**
  Raspberry Flavour
  Sugar free
  Gentle on tiny tummies when used as directed

- **Composition**
  Each 5ml contains: Paracetamol 160 mg

How to Use

For oral administration only. Always read the label before use.

Dosage

- Minimum dosing interval: 4 hours
- Children aged 1 month and above.
- Maximum daily dosage: 60 mg/kg presented in divided in divided doses of 10-15 mg/kg throughout the 24-hour period.
- No more than four doses in any 24-hour period.
- Maximum duration of continued use without medical advice: 3 days.

Warnings and Precautions:

- Contains Paracetamol. Do not use with any other paracetamol-containing products. The concomitant products. The concomitant use with other products containing paracetamol may lead to an overdose.
- Paracetamol overdose may cause liver failure which can lead to liver transplant or death.
- Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.
- Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index or are chronic heavy users of alcohol or have sepsis.
- In patients with glutathione depleted states, the use of paracetamol may increase the metabolic acidosis.
- If symptoms persist, medical advice must be sought.

- Keep out of sight and reach of children.

Overdose:

- Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and peak after 4 to 6 days.

- Overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Treatment

- Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

- If overdose is confirmed or suspected, seek immediate advice from your Poison Centre or refer patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.

- Where a Poison Information Centre is not available, refer patient to the nearest Emergency Medical Centre for management and expert treatment.

- Administration of N-acetylcysteine or methionine may be required.

Drug Interactions

- The anticoagulant effect of warfarin and other coumarins may be prolonged regular daily use of paracetamol with increased risk of occasional doses have no significant effect.

Contraindications

- This product is contraindicated in patients with a previous history of hypersensitivity to paracetamol or excipients.

Adverse Reactions

- Thrombocytopaenia, Anaphylaxis cutaneous hypersensitivity reactions including among other skin rashes, angioedema Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm in patients sensitive to aspirin and other NSAIDS, hepatic dysfunction.

Panadol Infant Drops

- Panadol Infant Drops is one of the trusted & recommended brands for children's pain & fever.

Overview

- **What does it relieve?**
  Fever
  Mild to moderate pain associated with:
  - Toothache
  - Headache
  - Sore throat
  - Vaccination
  - Common Childhood Ear Infections

- **Dosage form**
  Available in drops form

- **What are its features?**
  Includes a dropper for oral dosing which is marked in mL for easy dosage
  Raspberry Flavour & Cherry Vanilla Flavour
  Sugar free
  Gentle on tiny tummies when used as directed

- **Composition**
  Each 0.8 ml (one calibrated dropper) contains: Paracetamol 80 mg

How to Use

For oral administration only. Always read the label before use.

Dosage

- **For post-vaccination fever in Children 1 month – 3 months:**

  A single dose of 10 - 15 mg/kg for symptomatic relief of fever following vaccination. If a second dose is required, leave at least 4 hours between doses. Medical advice should be sought if fever persists after a second dose.

  It is recommended to follow local clinical practice guidelines where available.

- Minimum dosing interval: 4 hours

- Children aged 1 month and above.

- Maximum daily dosage: 60 mg/kg presented in divided in divided doses of 10-15 mg/kg throughout the 24-hour period.

- No more than four doses in any 24-hour period.

- Maximum duration of continued use without medical advice: 3 days.

Warnings and Precautions:

- Contains Paracetamol. Do not use with any other paracetamol-containing products. The concomitant products. The concomitant use with other products containing paracetamol may lead to an overdose.

- Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

- Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

- Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index or are chronic heavy users of alcohol or have sepsis.

- In patients with glutathione depleted states, the use of paracetamol may increase the metabolic acidosis.

- If symptoms persist, medical advice must be sought.

- Keep out of sight and reach of children.

Overdose:

- Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and peak after 4 to 6 days.

- Overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Treatment

- Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

- If overdose is confirmed or suspected, seek immediate advice from your Poison Centre or refer patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.

- Where a Poison Information Centre is not available, refer patient to the nearest Emergency Medical Centre for management and expert treatment.

- Administration of N-acetylcysteine or methionine may be required.

Drug Interactions

- The anticoagulant effect of warfarin and other coumarins may be prolonged regular daily use of paracetamol with increased risk of occasional doses have no significant effect.

Contraindications

- This product is contraindicated in patients with a previous history of hypersensitivity to paracetamol or excipients.

Adverse Reactions

- Thrombocytopaenia, Anaphylaxis cutaneous hypersensitivity reactions including among other skin rashes, angioedema Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm in patients sensitive to aspirin and other NSAIDS, hepatic dysfunction.

Panadol Extra

- Some days you want a more powerful pain reliever. Thankfully there's Panadol Extra with proven combination of Paracetamol and Caffeine that helps fight tough pain states.

Overview

- **What does it relieve?**

  - Headaches/Tension Headache
  - Migraine Headache
  - Osteoarthritis
  - Cold & Flu Symptoms
  - Period Pain
  - Muscular Aches
  - Sore Throat
  - Toothache

- **Dosage form**
  Available in tablet form

- **What are its features?**
  Panadol Extra provides fast and effective relief from pain and fever.
  No gluten, lactose or sugar, contains paracetamol, does not contain ibuprofen
  Suitable for elderly people

- **Composition**
  Each tablet contains: Paracetamol 500 mg and Caffeine 65 mg

How to Use

For oral administration only. Always read the label before use.

Dosage

- 1-2 tablets every 4 to 6 hours as required.
- Do not take more than 8 tablets in 24 hours.
- Do not take more frequently than every 4 hours.
- Do not exceed the stated dose.
- Do not give to children under 12 years.
- The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

Warnings and Precautions

- Contains Paracetamol. Do not use with any other paracetamol containing products. The concomitant use with other products containing paracetamol may lead to an overdose.
- Contains Caffeine. Avoid excessive intake of caffeine containing drinks (e.g. Tea, coffee etc.) when taking this medicine.
- Paracetamol overdose may cause liver failure which can lead to liver transplant or death.
- Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

- Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index or are chronic heavy users of alcohol or have sepsis.

- In patients with glutathione depleted states, the use of paracetamol may increase the metabolic acidosis.

- If symptoms persist, medical advice must be sought.

- Keep out of sight and reach of children.

- If cold & flu symptoms persist for longer than 7 days, medical advice should be sought. (Check this)

Overdose

Paracetamol

Symptoms and Signs

- Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and peak after 4 to 6 days.

- Overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Treatment

- Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

- If overdose is confirmed or suspected, seek immediate advice from your Poison Centre or refer patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.

- Where a Poison Information Centre is not available, refer patient to the nearest Emergency Medical Centre for management and expert treatment.

- Administration of N-acetylcysteine or methionine may be required.

Caffeine

Symptoms and Signs

- Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardiac arrhythmia, CNS stimulation (insomnia, restlessness, excitement, agitation, anxiety, tremors and convulsions).

- For clinically significant symptoms of caffeine overdose to occur with this product, the amount ingested would be associated with serious paracetamol-related liver toxicity.

Treatment

- No specific antidote is available, but supportive measures such as beta adrenoceptor antagonists to reverse the cardiotoxic effects may be used.

Drug Interactions

Paracetamol

- The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of occasional doses have no significant effect.

Caffeine

- Caffeine can increase the elimination of lithium from the body. Concomitant use is therefore not recommended.

Contraindications

- The product is contraindicated in patients with a previous history of hypersensitivity to paracetamol, caffeine, or excipients.

Pregnancy

This product is not recommended for use during pregnancy.

Paracetamol

- As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol. The lowest effective dose and shortest duration of treatment should be considered.

Caffeine

- Caffeine is not recommended for use during pregnancy due to the possible increased risk of 7 spontaneous abortion associated with caffeine consumption.

Lactation

This product is not recommended for use during breast feeding.

Paracetamol

- Paracetamol is excreted in breast milk but not in a clinically significant amount at recommended dosages.

Caffeine

- Caffeine excreted in breast milk may potentially have a stimulating effect on breast fed infants, but significant toxicity has not been observed.

Adverse Reactions

Paracetamol

- Thrombocytopaenia, Anaphylaxis cutaneous hypersensitivity reactions including among other skin rashes, angioedema, Stevens Johnsons syndrome, toxic epidermal necrolysis, bronchospasm in patients sensitive to aspirin and other NSAIDs, hepatic dysfunction.

Caffeine

- Nervousness, Dizziness, Palpitation, Insomnia, restlessness, anxiety and irritability, nervousness, gastrointestinal disturbances.

When recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects.

Panadol CF

Panadol CF contains a combination of an antipyretic/analgesic, a decongestant, and an antihistamine.

Overview

- **What does it relieve?**
  - Common Cold
  - Influenza
  - Fever associated with common cold and flu
  - Muscle ache
  - Nasal congestion
  - Sinus congestion
  - Headache and sinus pain

- **Dosage form**
  Available in tablet form

- **What are its features?**
  Provides Relief from symptoms of cold and flu
  Helps with Nasal congestion

- **Composition**
  Each tablet contains:
  Paracetamol BP 500 mg
  Pseudoephedrine Hydrochloride BP 60mg
  Chlorpheniramine Maleate BP 4mg

How to use?

For oral administration only. Always read the label before use.

Dosage

- Adults and children over 12 years
- One caplet every 4-6 hours as needed
- Children under 12 years:
  Do not give to children under 12 years of age
- Maximum dosage:
  Adults and children 4 caplets in 24 hours
  Elderly 3 caplets in 24 hours
- Minimum dosing interval: 4 hours
- Do not exceed stated dose of frequency of dosing.
- Should not be used other products containing paracetamol, decongestants, or antihistamines, including cough and cold preparation
- Use only under medical advice if symptoms persist for more than 7 days.
- The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment. Users should be advised to seek medical advice if symptoms persist for more than 7 days.

Warning and Precautions:

- Contains paracetamol. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure

which may require liver transplant or lead to death.

- Cases or hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index, are chronic heavy users of alcohol or have sepsis.

- Concomitant use of other cough and cold medicines, or antihistamines should be avoided.

- Chlorphenamine may increase the effects of alcohol and therefore concurrent use should be avoided.

- Consider the overall benefit-risk before using this product in patients with the following conditions:

    - Hepatic impairment. Underlying liver disease increases the risk of paracetamol-related liver damage.
    - Mild to moderate renal impairment
    - Glutathione depleted states, as the use of paracetamol may increase the risk of metabolic acidosis.
    - Cardiovascular disease
    - Arrhythmias
    - Hypertension
    - Hyperthyroidism
    - Diabetes
    - Prostatic enlargement
    - Psychosis
    - Pheochromocytoma
    - Raised intraocular pressure including glaucoma.
    - Epilepsy
    - Bronchitis, bronchiectasis, and bronchial asthma

- Use this product with caution:

    - in patients taking the following medications:

        - beta-blockers or other anti-hypertensives
        - vasoconstrictive agents such as ergot alkaloids
        - drugs which cause sedation, such as anxiolytics and hypnotics, as chlorphenamine may cause an increase in sedative effects.

    - when planning surgery. Acute perioperative hypertension may occur if volatile halogenated anaesthetics are used simultaneously with indirect sympathomimetic agents. It is recommended that pseudoephedrine treatment be stopped 24 hours before anaesthesia.

- There have been reports of acute systemic vasoconstrictive events with pseudoephedrine. Significant examples include:

    - Acute Coronary Syndrome (ACS): Symptoms include sudden chest pain, tightness, heavy sweating, and dyspnoea at rest.
    - Ischaemic colitis: Symptoms include sudden abdominal pain and rectal bleeding.
    - Posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS): Symptoms included sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment.

- Pseudoephedrine should be discontinued immediately, and medical advice sought if any signs/symptoms of vasoconstrictive events develop.

- Pseudoephedrine content of this product may result in a positive reaction during antidoping control tests.

- Children and the elderly are more likely to experience neurological anticholinergic effects and paradoxical excitation (e.g. increased energy,

restlessness, nervousness). Avoid use in elderly patients with confusion. Also, it is advised to use this product with caution in patients over the age of 60 years as the patients in this age group are at greater risk of adverse reactions due to decreased renal function, and more likely to experience unwanted reactions when using oral sympathomimetic agents.

- Keep out of sight and reach of children.

Overdose:

Management should be clinically indicated or as recommended by the national poison centres where available.

Paracetamol

- **Sign & Symptoms**

  Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and have peaked after 4 to 6 days. Paracetamol overdose may cause liver failure, which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

- **Treatment**

  Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

- If overdose is confirmed or suspected, seek immediate advice from your Poison Centre or refer the patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage. Where a Poison Information Centre is not available, refer the

patient to the nearest Emergency Medical Centre for management and expert treatment.

- Administration of N-acetylcysteine or methionine may be required.

Pseudoephedrine

- **Sign & Symptoms**

  Pseudoephedrine overdose may result in symptoms due to central nervous system and cardiovascular stimulation e.g. excitement, restlessness, hallucinations, hypertension, and arrhythmias. In severe cases, psychosis, convulsions, coma, and hypertensive crisis may occur. Serum potassium level may be low due to extracellular shifts in potassium.

- **Treatment**

  Treatment should consist of standard supportive measures. Beta-blockers should reverse the cardiovascular complications and hypokalemia.

Chlorphenamine

- **Symptoms and Sign**

  Chlorphenamine overdose is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include toxic psychosis, convulsions, apnoea, dystonic reactions, and cardiovascular collapse including arrhythmias.

- **Treatment**

  Treatment should be supportive and directed towards specific symptoms.

Drug Interactions

- Concomitant administration of pseudoephedrine and MAOIs or use within two weeks of stopping of a MAOI may lead to hypertensive crisis. The anticholinergic effects of chlorphenamine may be intensified by MAOIs.

- The oxazolidinone class of antibiotics (including furazolidone and linezolid) are known to cause a dose related inhibition of monoamine oxidase. Therefore, they should not be taken with pseudoephedrine as there is a potential to cause hypertensive crisis.

- Concomitant use of pseudoephedrine with sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like medicines, may occasionally cause a rise in blood pressure.

- Pseudoephedrine may antagonise the effect of certain classes of antihypertensives such as beta-blockers, methyl-dopa, reserpine, debrisoquine, guanethidine.

- Pseudoephedrine may interact with halogenated anaesthetics and may cause acute perioperative hypertension.

- Concomitant administration of pseudoephedrine with vasoconstrictive agents including ergot derivatives (such as bromocriptine, pergolide, lisuride, cabergoline, ergotamine, dihydroergotamine and methysergide) may cause an increased risk of ergotism.

- Concurrent use of chlorphenamine and hypnotics or anxiolytics may potentiate drowsiness. Concurrent use of alcohol may have a similar effect.

- Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

- The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol-containing products with increased risk of bleeding; occasional doses have no significant effect.

Contraindications:

The product is contraindicated in patients:

- with a previous history of hypersensitivity to paracetamol, pseudoephedrine, chlorphenamine, or to any excipients.
- with hypertension of either 180 mmHg systolic or 120 mmHg diastolic, or higher, or coronary artery disease.
- With sever renal impairment (GFR < 30mL/min)
- who are receiving other sympathomimetics (such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like medicines).
- who are taking or have taken monoamine oxidase inhibitors (MAOIs) in the last two weeks.
- who are taking oxazolidinone class of antibiotics including furazolidone and linezolid.

Pregnancy and Lactation

Fertility

There are insufficient data on the potential effects of this product on fertility.

Pregnancy

There are insufficient data regarding the use of the product in pregnant women. Avoid the use of the product during pregnancy, unless the benefits to the pregnant woman outweigh the risks to the foetus. If used, the lowest effective dose and shortest duration of treatment should be considered.

Paracetamol

- As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol.

Pseudoephedrine

- Although pseudoephedrine has been in widespread use for many years, its safe use during pregnancy has not been established.

Chlorphenamine

- There are no adequate data from the use of chlorphenamine maleate in pregnant women. The potential risk for humans is unknown.

Lactation

This product should not be used whilst breastfeeding, unless the benefits to the mother outweigh the risks to the infant. If used, the lowest effective dose and shortest duration of treatment should be considered.

Paracetamol

- Paracetamol is excreted in breast milk but not in a clinically significant amount at recommended dosages.

Pseudoephedrine

- Pseudoephedrine is excreted in breast milk in small amounts but the effect of this on breast fed infants is unknown.

Chlorphenamine

- Chlorphenamine maleate may inhibit lactation and may be secreted in breast milk.

Ability to Perform Task that required Judgement, motor, or cognitive skills.

- This product may cause drowsiness, dizziness, blurred vision, and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery.

Adverse Reactions

The following convention has been utilized for the classification of the frequency of adverse reactions: very common (≥ 1/10), common (≥ 1/100, < 1/10), uncommon (≥ 1/1000, < 1/100), rare (≥ 1/10000, < 1/100), very rare (< 1/10000), not known (cannot be estimated from the available data). Whenever possible, adverse reactions observed in clinical trials and those reported from post-marketing experience at therapeutic/labelled doses have been presented separately. These reactions are tabulated by MedDRA System Organ Class (SOC). As adverse reactions from post-marketing experience are reported voluntarily from a population of uncertain size, the frequency of these reactions is unknown but considered likely to be rare or very rare.

Paracetamol

- Thrombocytopenia, Anaphylaxis Cutaneous hypersensitivity reactions including, among others, Toxic Epidermal Necrolysis (TEN), Stevens-Johnson syndrome (SJS), angioedema and skin rashes, Bronchospasm in patients sensitive to acetylsalicylic acid and other NSAIDs, Hepatic dysfunction.

Pseudoephedrine

- Nervousness, Insomnia, Agitation, Restlessness, Hallucinations (particularly in children) Anxiety, Dizziness, Headache, Tremor, Tachycardia, Palpitations, Increased blood pressure*, Vomiting, Dry mouth, Nausea, Acute generalised exanthematous pustulosis (AGEP), allergic dermatitis**, rash, Urinary retention***, dysuria.

  *Increases in systolic blood pressure have been observed. At therapeutic doses, the effects of pseudoephedrine on blood pressure are not clinically significant.

  **A variety of allergic skin reactions, with or without systemic features such as bronchospasm and angioedema have been reported following use of pseudoephedrine.

  ***Urinary retention is most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy.

Chlorphenamine

- Anaphylactic reactions, Allergic reactions, Anorexia, Confusion, excitation, irritability, nightmares paradoxical excitation (e.g. increased energy, restlessness, nervousness), Sedation, somnolence, Disturbance in attention, abnormal coordination, dizziness, headache, Blurred vision, Hypotension, Thickening of bronchial secretions, Nausea, dry mouth, Vomiting, abdominal pain, diarrhoea, dyspepsia, Exfoliative dermatitis, rash, urticaria, photosensitivity, Muscle twitching, muscle weakness, Urinary retention, Fatigue, Chest tightness.

Panadol Plain

Panadol can be used for relieving fever and/or for the treatment of mild to moderate pain including headache, migraine, muscle ache, dysmenorrhea, sore throat, musculoskeletal pain and pain after dental procedures/ tooth extraction, toothache, and pain of osteoarthritis.

Overview

- **What does it relieve?**
  - Fever
  - Headache/Tension headache
  - Toothache
  - Migraine Headache
  - Musculoskeletal pain
  - Osteoarthritis
  - Low Back Strain

- **Dosage form**
  Available in tablet form

- **What are its features?**
  Panadol provides effective relief from pain and fever
  No gluten, lactose, or sugar, contains paracetamol, does not contain ibuprofen
  Suitable for elderly people
  Unlikely to cause stomach irritation when used as directed

- **Composition**
  Each tablet contains: Paracetamol 500 mg

How to use?

For oral administration only. Always read the label before use.

Dosage

Adults (including the elderly) and children aged 12 years and over:

- 1-2 tablets every 4-6 hours as required.
  Do not take more than 8 tablets (4000 mg Paracetamol) in 24 hours.

- Do not take more frequently than every 4 hours.
- Do not exceed the stated dose.

- The lowest dose necessary to achieve efficacy should be used.

- Should not be used with other paracetamol-containing products.

Children 6 to 11 years:

6 – 8 years: ½ tablet (250 mg) every 4 to 6 hours

9-11 years: 1 tablet (500 mg) every 4 to 6 hours

- Maximum daily dose: 60 mg/kg presented in divided doses of 10-15 mg/kg throughout the 24-hour period.

- Do not take frequently than every 4 hours.

- Do not exceed the stated dose.

- Minimum dosing interval: 4 hours

- Maximum duration of continued use without medical advice: 3 days

- Should not be used with other paracetamol-containing products.

Children under 6 years:

Not recommended for children under the age of 6 year.

Warning and Precautions

- Contains paracetamol. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose.

- Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

- Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

- Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index, are chronic heavy users of alcohol or have sepsis.

- In patients with glutathione depleted states as the use of paracetamol may increase the risk of metabolic acidosis.

- Do not use this medicine if you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

- If symptoms persist, medical advice must be sought.

- Keep out of sight and reach of children.

Overdose

- Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and peak after 4 to 6 days.

- Overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Treatment

- Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

- If overdose is confirmed or suspected, seek immediate advice from your Poison Centre or refer patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.

- Where a Poison Information Centre is not available, refer patient to the nearest Emergency Medical Centre for management and expert treatment.

- Administration of N-acetylcysteine or methionine may be required.

Pregnancy and Lactation

Pregnancy

- As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol. The lowest effective dose and shortest duration of treatment should be considered.

Lactation

- Paracetamol is excreted in breast milk but not in a clinically significant amount at recommended dosages. Available published data do not contraindicate breastfeeding.

Adverse Reactions

Thrombocytopenia, Anaphylaxis cutaneous hypersensitivity reactions including among others skin lashes, angioedema, Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm in patients sensitive to aspirin and other NSAIDs, hepatic dysfunction.

Panadol Night

For the temporary relief of fever and pain, when associated with sleeping, difficulty, for example: rheumatic and muscular pain, arthritis, backache, toothache, migraine, headache, period pain and neuralgia.

- **What does it relieve?**

  - Headache
  - Migraine
  - Muscle ache
  - Dysmenorrhoea
  - Sore throat
  - Musculoskeletal pain
  - Fever and pain associated with vaccination/immunisation
  - Pain after dental procedures/tooth extraction
  - Toothache
  - Earache / Otalgia
  - Respiratory tract infections including cold and flu
  - Osteoarthritis pain
  - Cough and cold symptoms such as sneezing, runny nose, itchy nose or throat, minor throat and bronchial irritation

- **Dosage form**
  Available in tablet form

- **What are its features?**
  Panadol Night provides temporary relief of fever and pain, when associated with sleeping difficulty.

- **Composition**
  Each film coated tablet contains:
  Paracetamol 500 mg and Diphenhydramine Hydrochloride 25 mg

How to Use

For oral administration only. Always read the label before use.

Dosage & Administration:

- Do not exceed the stated dose.
- Do not use in children under 12 years of age without medical advice.
- Other products containing paracetamol may be taken during the day, but the total daily dose of paracetamol must not exceed 4000mg (including this product) in any 24-hour period. Allow at least four hours between taking any paracetamol-containing product and this product.
- Should not be used with other antihistamine-containing preparations, including those used on the skin.
- The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.
- Adults (including the elderly) and children aged 12 years and over:
  2 tablets (1000mg paracetamol, 50mg diphenhydramine HCl) 20 minutes before going to bed.
- Maximum daily dose: Two tablets (total of 1000mg paracetamol, and 50mg diphenhydramine HCl) in 24 hours.
- Do not take for more than 14 consecutive nights without medical advice

Warnings and Precautions:

All formulations:

- Contains paracetamol. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure which may require liver transplant or lead to death.

- Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index, are chronic heavy users of alcohol or have sepsis.

- Avoid use with other antihistamine-containing preparations, including topical antihistamines and other cough and cold medicines.

- Avoid concurrent use with alcohol, as diphenhydramine may increase the sedative effects of alcohol. (see Interactions).

- Avoid use in in elderly patients with confusion. Use with caution in the elderly, who are more likely to experience adverse effects.

- Medical advice should be sought before taking in patients with:

    - Hepatic or renal impairment. Underlying liver disease increases the risk of paracetamol-related liver damage.

    - Glutathione depleted states as the use of paracetamol may increase the risk of metabolic acidosis.

- Concurrent use of drugs which cause sedation such as tranquillizers, hypnotics and anxiolytics as diphenhydramine may cause an increase in sedative effects (see Interactions).

- Use with caution in:

  - patients with epilepsy or seizure disorders, myasthenia gravis, narrow-angle glaucoma, prostatic hypertrophy, urinary retention, asthma, bronchitis, and chronic obstructive pulmonary disease (COPD) and moderate to severe hepatic impairment and moderate to severe renal impairment.

  - patients taking monoamine oxidase inhibitors (MAOIs) or within 2 weeks of stopping an MAOI (see Interactions).

  - patients taking other drugs with antimuscarinic properties (e.g. atropine, tricyclic antidepressants (see Interactions).

- If symptoms persist, medical advice must be sought.

- Keep out of sight and reach of children.

- **In addition, the following apply to specific presentations**:

- **For products containing lactose:** Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Overdose:

Paracetamol

Symptoms and signs

Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and peak after 4 to 6 days.

Overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis have been observed, usually with hepatic dysfunction and liver toxicity.

Treatment
Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present. Administration of N-acetylcysteine or methionine may be required.

Diphenhydramine

Symptoms and signs

Diphenhydramine overdose is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include mydriasis, fever, flushing, agitation, tremor, dystonic reactions, hallucinations and ECG changes including QT prolongation. Large overdose may cause rhabdomyolysis, convulsions, delirium, toxic psychosis, arrhythmias, coma, and cardiovascular collapse.

Treatment

Treatment should be supportive and directed towards specific symptoms. Convulsions and marked CNS stimulation should be treated with parenteral

diazepam. The intravenous use of physostigmine may be efficacious in antagonizing severe anticholinergic symptoms. Further management should be as clinically indicated or as recommended by the national poison centres where applicable.

General considerations

If overdose is confirmed or suspected, seek immediate advice from your Poison Centre (include contact details: Phone + Website + Email) and refer patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.

Where a Poison Information Centre is not available, refer patient to the nearest Emergency Medical Centre for management and expert treatment.

Contraindications:

- If you have ever had an allergic reaction to paracetamol, diphenhydramine hydrochloride or to any of the other ingredients.
- If you have porphyria (too much of the pigment called porphyrin which may discolour the urine).
- If you have taken another medicine containing paracetamol in the last 4 hours.

Contains Paracetamol:

Do not take with any other antihistamine containing products, including those used on your skin or in cough and cold medicines.

Pregnancy & Lactation:

Fertility

No relevant data available.

Pregnancy

This product should not be used during pregnancy unless the expected benefit justifies the potential risk to the foetus. The lowest effective dose and shortest duration of treatment should be considered.

Paracetamol

As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol.

Diphenhydramine

There are no adequate data from the use of diphenhydramine in pregnant women. The available non-clinical data suggest the potential for diphenhydramine to induce adverse developmental effects when administered to mice. The potential risk for humans is unknown. Diphenhydramine crosses the placenta. Use of sedating antihistamines during the third trimester may result in reactions in the newborn or premature neonates.

Lactation

This product should not be used whilst breast feeding unless the expected benefit justifies the potential risk to the newborn.

Paracetamol
Paracetamol is excreted in breast milk but not in a clinically significant amount at recommended dosages.

Diphenhydramine

Diphenhydramine has been detected in breast milk, but the effect of this on breastfed infants is unknown.

Ability to perform tasks that require Judgement, Motor or Cognitive Skills

May cause drowsiness, dizziness, blurred vision, cognitive and psychomotor impairment, which can seriously affect the patient's ability to drive or operate machinery. If affected, do not drive, or operate machinery.

Drug Interactions:

- Potentially clinically significant drug interactions are listed below.

- The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

- Diphenhydramine may potentiate the sedative effects of alcohol, other CNS depressants (e.g. codeine, tranquillizers, hypnotics and anxiolytics) and other antihistamines (see Warnings and Precautions).

- Monoamine oxidase inhibitors may prolong and intensify the anticholinergic effects of diphenhydramine (see Warnings and Precautions).

- As diphenhydramine has some anticholinergic activity, the effects of some anticholinergic drugs (e.g. atropine, tricyclic antidepressants) may be potentiated. This may result in tachycardia, dry mouth, blurred vision, gastrointestinal disturbances (e.g. colic), urinary retention, and headache (see Warnings and Precautions).

- Diphenhydramine is an inhibitor of the cytochrome p450 isoenzyme CYP2D6. Therefore, there may be a potential for interaction with drugs which are primarily metabolised by CYP2D6, such as metoprolol and venlafaxine.

Adverse Reactions:

The following convention has been utilized for the classification of the frequency of adverse reactions: very common (≥ 1/10), common (≥ 1/100, < 1/10), uncommon (≥ 1/1000, < 1/100), rare (≥ 1/10000, < 1/100), very rare (<1/10000), not known (cannot be estimated from the available data).

Paracetamol

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated by MedDRA System Organ Class.

As these reactions are reported voluntarily from a population of uncertain size, the frequency of these reactions is not known but likely to be very rare.

Thrombocytopaenia, Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes, angioedema, Stevens-Johnson syndrome and Toxic Epidermal Necrolysis, Bronchospasm in patients sensitive to aspirin and other NSAIDs, Hepatic dysfunction

Diphenhydramine

Fatigue, Sedation, Somnolence, Disturbance in attention, Unsteadiness, Dizziness, Dry mouth, Hypersensitivity reactions including rash, urticaria, dyspnoea and angioedema. Confusion, Paradoxical excitation (e.g. increased energy, restlessness, nervousness), Convulsions, Headache, Paraesthesia, Dyskinesias, Blurred vision, Tachycardia, Palpitations, thickening of bronchial secretions, Gastrointestinal disturbance including nausea, vomiting, Muscle twitching, Urinary difficulty, Urinary retention.

Panadol Extend

Panadol Extend can be used for up to 8 hours of relieving muscle pain, fever, joint pain, back pain, and toothache.

Overview

- **What does it relieve?**

  - Headache
  - Migraine
  - Muscle ache
  - Dysmenorrhoea
  - Sore throat
  - Musculoskeletal pain
  - Fever and pain associated with vaccination/immunisation
  - Pain after dental procedures / tooth extraction
  - Toothache
  - Earache / Otalgia
  - Respiratory tract infections including cold and
  - Osteoarthritis pain.

- **Dosage form**
  Available in tablet form

- **What are its features?**
  No gluten, lactose, or sugar, contains paracetamol, does not contain ibuprofen
  Suitable for elderly people
  Unlikely to cause stomach irritation when used as directed

- **Composition:**
  Each modified release tablet contains: Paracetamol 665mg

How to use?

For oral administration only. Always read the label before use.

Dosage

- Do not exceed the stated dose.
- The lowest dose necessary to achieve efficacy should be used with the shortest duration of treatment.
- Oral administration only.
- Minimum dosing interval: 6 hours.
- Swallow whole tablet. Do not chew or suck, as it impairs the sustained release properties.
- Maximum daily dose: 4000 mg (3990 mg for 665 mg formulation).

Adults (including the elderly) and children aged 12 years and over:

1330 mg paracetamol (2 tablets) taken three times a day, every 6 to 8 hours as required, up to a maximum of 6 tablets in any 24-hour period.
Can be taken with or without food.

Children under 12 years:

Not recommended for children under the age of 12 years.

Warning and Precautions

- Contains paracetamol. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose.

- Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

- Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

- Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index, are chronic heavy users of alcohol or have sepsis.

- In patients with glutathione depleted states as the use of paracetamol may increase the risk of metabolic acidosis.

- Do not use this medicine if you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

- If symptoms persist, medical advice must be sought.

- Keep out of sight and reach of children.

- Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and peak after 4 to 6 days.

- Because paracetamol 665 mg modified release tablets are a sustained-release product, absorption will be prolonged in overdose, the maximum plasma concentration may occur later, and high concentrations, in particular after large doses, may persist for several days.

- The usual protocols of sampling and treatment regimen used in the management of overdose with immediate release paracetamol formulations are therefore not adequate.

Overdose

- Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and peak after 4 to 6 days.

- Overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Treatment

- Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

- If overdose is confirmed or suspected, seek immediate advice from your Poison Centre or refer patient to nearest Emergency Medical Centre for management and expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage.

- Where a Poison Information Centre is not available, refer patient to the nearest Emergency Medical Centre for management and expert treatment.

- Administration of N-acetylcysteine or methionine may be required.

- Experience following overdose with paracetamol indicates that the clinical signs of liver injury usually occur after 24 to 48 hours and have peaked after 4 to 6 days.

- Because paracetamol 665 mg modified release tablets are a sustained-release product, absorption will be prolonged in overdose, the maximum plasma concentration may occur later, and high concentrations, in particular after large doses, may persist for several days.

- The usual protocols of sampling and treatment regimens used in the management of overdose with immediate release paracetamol formulations are therefore not adequate.

- Where overdose with ≥10 g paracetamol 665 mg modified release tablets is known or suspected, or where dose is unknown, treatment with antidote (usually N-acetylcysteine) should be started immediately.

- Where <10 g paracetamol 665 mg modified release tablets have been ingested and time since ingestion is known, multiple serum paracetamol samples should be taken at suitable intervals (e.g. 4, 6, and 8 hours after ingestion). Further samples should be considered if serum paracetamol concentrations are not declining. If serum paracetamol levels exceed the treatment nomogram at any timepoint, treatment with antidote (usually N-acetylcysteine) is indicated.

- If time since ingestion is unknown or serum paracetamol concentration cannot be obtained within 8 hours of the overdose, it is recommended that treatment with antidote (usually N-acetylcysteine) should be initiated without waiting for serum paracetamol concentrations to be available.

- Antidote should be dosed as recommended by the local Poison Information Centre.

Pregnancy and Lactation

Pregnancy

- As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol. The lowest effective dose and shortest duration of treatment should be considered.

Lactation

- Paracetamol is excreted in breast milk but not in a clinically significant amount at recommended dosages. Available published data do not contraindicate breastfeeding.

Adverse Reactions

Thrombocytopenia, Anaphylaxis cutaneous hypersensitivity reactions including among others skin lashes, angioedema, Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm in patients sensitive to aspirin and other NSAIDs, hepatic dysfunction.