

## Package leaflet: Information for the patient

### Panadol Head Cold Powder for Oral Solution Paracetamol 600mg, Ascorbic acid 40mg

**Read all of this leaflet carefully because it contains important information for you.**

Always take this medicine as described in this leaflet or as your healthcare professional has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after three days.

#### **What is in this leaflet:**

- 1) What Panadol Head Cold is and what it is used for
- 2) What you need to know before you take Panadol Head Cold
- 3) How to take Panadol Head Cold
- 4) Possible side effects
- 5) How to store and dispose of Panadol Head Cold
- 6) Contents of the pack and other information

#### **1) What Panadol Head Cold is and what it is used for**

Panadol Head Cold contains paracetamol and ascorbic acid (Vitamin C). Paracetamol is a pain killing drug that also helps to reduce your temperature when you have a fever. The Vitamin C supplements your natural Vitamin C levels which may drop when you have a viral infection like a cold.

Panadol Head Cold provides relief from the symptoms of flu, fever, chills and feverish colds including headache, aches and pains.

#### **2) What you need to know before you take Panadol Head Cold DO NOT take Panadol Head Cold if you:**

- are allergic to paracetamol, ascorbic acid (Vitamin C) or any of the other ingredients listed in section 6
- are taking any other paracetamol containing products
- suffer from severe liver or kidney problems

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Panadol Head Cold:

- If you suffer from liver or kidney problems.
- If you have a severe infection, are severely malnourished, have low body weight (less than 50 kg) or are a chronic heavy alcohol user as this may increase the risk of **liver damage**.
- If you have glutathione deficiency.
- If you have a high fever, or if your symptoms get worse or persist for more than a few days.

#### **During treatment with Panadol Head Cold, tell your doctor straight away:**

- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Contact a doctor immediately if you get a combination of these symptoms.

#### **Children and adolescents**

Panadol Head Cold should not be taken by children and adolescents under 16 years of age, except on medical advice.

### **Other medicines and Panadol Head Cold**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Particularly:

- An antibiotic called chloramphenicol.
- Metoclopramide or domperidone used to treat nausea and vomiting.
- Cholestyramine used to lower your blood cholesterol.
- Medicines that thin the blood such as warfarin. Paracetamol may increase their effect.
- Any other medicines that might affect your liver.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Always check the leaflet that comes with your other medicine.

### **Pregnancy and breastfeeding**

If necessary, Panadol Head Cold may be taken during pregnancy and breastfeeding. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more often. Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Panadol Head Cold has not been shown to affect your ability to drive or operate machinery.

### **Panadol Head Cold contains sucrose and sodium:**

- Contains 3.7 g of sucrose per dose. Talk to your doctor before taking this medicine if you have diabetes or if you suffer from sugar intolerance or sugar absorption problems.
- Contains 113 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 6% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

### **3) How to take Panadol Head Cold**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### **Adults (including elderly) and children aged 16 years and over:**

Dissolve one sachet of Panadol Head Cold in a cup or mug of hot water. Take one sachet every 4 to 6 hours. DO not take more frequently than every 4 hours.

Do not take more than 6 sachets in 24 hours.

Always use the lowest effective dose and shortest duration of treatment to relieve your symptoms.

NOT SUITABLE FOR CHILDREN UNDER 16 YEARS OF AGE.

Do not exceed the stated dose.

If symptoms persist consult your doctor. Prolonged use without medical supervision may be harmful. This product should be used when clearly necessary.

#### **If you take more Panadol Head Cold than you should:**

**Immediate medical advice should be sought in the event of an overdose because of the risk of irreversible liver damage.**

**Contact your doctor immediately** and say exactly how much you have taken. Your doctor will advise you what to do. It is

important to contact your doctor even if you feel well.

**If you forget to take Panadol Head Cold:**

Do **NOT** take a double dose to make up for a dose you have forgotten. You must allow at least 4 hours between doses.

**4. Possible side effects**

Like all medicines, Panadol Head Cold can have side effects, although not everybody gets them. Skin rash and other allergic effects can occasionally occur. Very rare cases of serious skin reactions have been reported.

Stop taking this medicine and tell your doctor immediately if:

- you experience serious skin reactions, very rare cases of which have been reported.
- you experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
- you experience a skin rash or peeling of the skin, which may be accompanied by mouth ulcers.
- you have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories and experience a similar reaction to this product.
- you experience unexplained bruising or bleeding.
- you experience nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.

These reactions are very rare.

A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2). The frequency of this side effect is not known (cannot be estimated from the available data).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store and dispose of this medicine**

- keep out of the sight and reach of children
- do not use this medicine after the expiry date (EXP) which is stated on the outer carton and sachets. The expiry date refers to the last day of that month.
- do not store this medicine above 25°C
- medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Contents of the pack and other information What Panadol Head Cold contains:**

Each sachet of Panadol Head Cold contains 600mg of paracetamol and 40mg of ascorbic acid (Vitamin C). The sachets also contain sucrose, citric acid anhydrous, sodium citrate, maize starch (dried), saccharin sodium, sodium cyclamate, anhydrous colloidal silica, lemon flavour (containing maltodextrins) and natural curcumin (E100)

**What Panadol Head Cold looks like and contents of the pack**

Panadol Head Cold is an off white powder with an odour of lemon which comes in sachets. They are available in packs of 5 or 10 sachets.

**Marketing Authorisation holder and Manufacturer**

**The Marketing Authorisation Holder is:**

Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland and all enquiries should be sent to this address.

**The Manufacturer is:**

SmithKline Beecham S.A. Avda de Ajalvir Km 2,500, 28806 Alcala de Henares, Madrid, Spain.

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