Package leaflet: Information for the patient

PANADOL MAX STRENGTH COLD & FLU HOT BERRY PLUS VITAMIN C
Powder for Oral Solution
Paracetamol 1000 mg
Ascorbic Acid 70 mg

Read all of this leaflet carefully before you start taking this medicine 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

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1. What Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C is and what it is used for

Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C 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 Max Strength Cold & Flu Hot Berry plus Vitamin C 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 Max Strength Cold & Flu Hot Berry plus Vitamin C

<u>DO NOT take</u> Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C 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.
- Are under 16 years old
- Suffer from severe liver or kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C:

- 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) 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 Max Strength Cold & Flu Hot Berry plus Vitamin C, 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 Max Strength Cold & Flu Hot Berry plus Vitamin C should not be taken by children under 16 years of age, except on medical advice.

Other medicines and Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C:

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 and Fertility

If necessary, Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C 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.

Driving and using machines

Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C has not been shown to affect your ability to drive or operate machinery.

Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C contains sucrose, sodium, aspartame and colourings:

- Contains 5 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 0.12g 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 is you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.
- Contains 80 mg aspartame (E 951) per dose. It is a source of phenylalanine. May be harmful for people phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds ups because the body cannot remove it properly.
- Contains the colours carmoisine (E 122) and sunset yellow (E 110), which may cause allergic reactions including asthma.

3. How to take Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C

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

The recommended dose of Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C is:

Adults (including elderly) and children aged 16 years and over:
Dissolve one sachet of Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C in a cup or mug of hot water. Take one sachet every 4 hours.
Do not take more frequently than every 4 hours.
Do not take more than 4 sachets in 24 hours.
Do not exceed the stated dose.
If symptoms persist consult your doctor.
Prolonged use without medical supervision may be harmful.
This product should only be used when clearly necessary.

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

Use in children

Not suitable for children under 16 years of age.

If you take more Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C than you should

Immediate medical advice should be sought in the event of overdosage 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 Max Strength Cold & Flu Hot Berry plus Vitamin C

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 Max Strength Cold & Flu Hot Berry plus Vitamin C can have side effects, although not everybody gets them.

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.

Other side effects: A serious condition that can make blood more acidic (called

metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

These reactions are very rare.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Ireland: HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C

- 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 the month.
- Do not store this medicine above25°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 further information

What Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C contains:
Each sachet of Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C contains 1000mg of paracetamol and 70mg of ascorbic acid (Vitamin C).

The sachets also contain sucrose, sodium citrate, anhydrous tartaric acid, aspartame (E951), berry fruits flavour (including menthol) and blackcurrant colouring (including the colours carmoisine (E122), Sunset Yellow (E110) green S (E142)).

What Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C looks like and contents of the pack:
Panadol Max Strength Cold & Flu Hot Berry plus Vitamin C is a pale pink powder 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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