

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

PERFALGAN 1 g Solution for Infusion

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU ARE GIVEN PERFALGAN 1 g

Solution for Infusion:

- Keep this leaflet. You may want to read it again.
- If you have further questions, please contact your doctor or pharmacist.
- PERFALGAN 1 g has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT PERFALGAN 1 g CONTAINS

PERFALGAN 1 g: Each 100 ml vial contains 1 g paracetamol as active ingredient.

Preservative: Cysteine hydrochloride monohydrate 0,025 % *m/v*

Inactive excipients include mannitol, cysteine hydrochloride, sodium hydroxide, hydrochloric acid, water for injections.

WHAT PERFALGAN 1 g IS USED FOR

PERFALGAN 1 g is an analgesic (it relieves pain), so it is used for the short-term treatment of mild to moderate pain, especially following dental procedures and minor orthopaedic surgery and the short-term treatment of fever where the oral route is unsuitable.

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It is restricted to use in adults and children weighing more than 33 kg (approximately 11 years old).

BEFORE YOU ARE GIVEN PERFALGAN 1 g

You should not be given PERFALGAN 1 g

- If you are hypersensitive (allergic) to paracetamol, or any of the other ingredients
- If you have severe liver disease

Special care should be taken with PERFALGAN 1 g:

- If you have liver or kidney disease, or alcohol abuse
- If you are taking other medicines containing paracetamol including prescription and non-prescription medicines
- If you have nutritional problems (malnutrition) or dehydration
- If you are pregnant or breastfeeding
- If you are taking or have recently taken medication, especially probenecid, salicylamide or enzyme-inducing substances

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before receiving this medicine.

Important information about some of the ingredients of PERFALGAN 1 g

PERFALGAN 1 g contains mannitol and may have a laxative effect.

Taking other medicines with PERFALGAN 1 g

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Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

This medicine contains paracetamol, and this must be taken into account if other medicines containing paracetamol are taken, in order not to exceed the recommended daily dose (see 'HOW SHOULD PERFALGAN 1 g BE USED'). Inform your doctor if you are taking other medicines containing paracetamol.

A dose reduction should be considered for concomitant treatment with probenecid.

Please inform your doctor or pharmacist if you are taking oral anticoagulants. Closer check-ups of the effect of the anticoagulant might be necessary.

HOW TO USE PERFALGAN 1 g

DO NOT EXCEED THE RECOMMENDED DOSE.

You will not be expected to give yourself PERFALGAN 1 g. It will be given to you by a person who is qualified to do so.

The paracetamol solution is administered as an intravenous infusion over 15 minutes. Your doctor will prescribe the appropriate dose for you. The dose you are given is based on your weight.

Do not share medicines prescribed for you, with others.

If you use more PERFALGAN 1 g than you should:

Since a healthcare professional will administer this medicine, he/she will control the dosage.

However, in the event of overdose your doctor will manage the overdose.

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PERFALGAN 1 g contains paracetamol which may be fatal in overdose. In the event of over dosage or suspected over dosage and notwithstanding the fact that a person may be asymptomatic, the nearest doctor, hospital or Poison Center must be contacted immediately.

POSSIBLE SIDE EFFECTS

PERFALGAN 1 g can have side effects.

Not all side effects reported for PERFALGAN 1 g are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PERFALGAN 1 g, please consult your doctor, pharmacist or other health care professional for advice.

The following side effects may occur:

- Malaise
- A drop in blood pressure
- Changes in laboratory test results, where abnormally high levels of liver enzymes are found during blood tests. Follow up blood tests may be needed later
- A serious skin reaction or allergic reaction, stop the treatment immediately and inform your doctor
- Other changes in laboratory test results have been seen which results in regular blood checks: abnormally low levels of some types of blood cells (platelets, white cells), possibly leading to bleeding from the nose or gums. Should this occur, inform your doctor

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- Redness of the skin, flushing, itching and abnormally rapid beating of the heart, have been reported
- Pain and burning sensation at the injection site may occur

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF PERFALGAN 1 g

- Store all medicines out of reach of children.
- Store at or below 30 °C. Do not refrigerate or freeze. Once opened, the vial should be used immediately.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Do not use after the expiry date stated on the label.

PRESENTATION OF PERFALGAN 1 g

PERFALGAN 1 g is available in 100 ml clear Type II glass vials in packs of 12 vials.

IDENTIFICATION OF PERFALGAN 1 g

The solution for infusion is clear and slightly yellowish.

REGISTRATION NUMBER

A38/2.7/0561

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