

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

ASPEN PARACETAMOL 1g IV solution for infusion

Paracetamol

Sugar free

Read all of this leaflet carefully before ASPEN PARACETAMOL 1g IV is administered to you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What ASPEN PARACETAMOL 1g IV is and what it is used for
2. What you need to know before ASPEN PARACETAMOL 1g IV is administered to you
3. How ASPEN PARACETAMOL 1g IV will be administered to you
4. Possible side effects
5. How to store ASPEN PARACETAMOL 1g IV
6. Contents of the pack and other information

1. What PROPRIETARY NAME is and what it is used for

ASPEN PARACETAMOL 1g IV is a sterile solution containing paracetamol, which is an analgesic (it relieves pain) and antipyretic (it lowers fever).

It is used for the short-term treatment (not exceeding 24 hours) of mild to moderate pain, e.g. after dental procedures or minor orthopaedic procedures and for the short term treatment of fever in patients who cannot take oral paracetamol treatment.

2. What you need to know before ASPEN PARACETAMOL 1g IV is administered to you

ASPEN PARACETAMOL 1g IV should not be administered:

- if you are hypersensitive (allergic) to paracetamol, propacetamol hydrochloride (a prodrug of paracetamol) or any of the other ingredients of ASPEN PARACETAMOL 1g IV (listed in section 6).
- if you suffer from severe liver disease, including alcoholic liver disease.
- in children weighing less than 33 kg (approximately 11 years old).

Warnings and precautions

ASPEN PARACETAMOL 1G IV contains paracetamol which may be fatal in overdose. In the event of overdose or suspected overdose, and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Your medical doctor will switch you to a suitable oral formulation as soon as possible.

Tell your doctor or healthcare provider before being given ASPEN PARACETAMOL

1g IV:

- if you take other medicines that contain paracetamol.
- if you are recovering from liver disease.
- if you have a liver condition in which the liver doesn't properly process bilirubin called Gilbert's syndrome.
- if you suffer from kidney disease.
- if you suffer from chronic alcoholism or excessive alcohol intake.
- if you suffer from dehydration (where your body does not have as much water and fluids as it should) or hypovolaemia (a state of decreased blood volume).
- if you have chronic malnutrition (a condition where your body does not have enough nutrients).
- if you suffer from bulimia or anorexia (eating disorders).
- if you suffer from cachexia or wasting syndrome (is loss of weight, muscle atrophy, fatigue, weakness, and significant loss of appetite in someone who is not actively trying to lose weight).
- if you suffer from glucose-6-phosphate dehydrogenase deficiency (An inherited condition, G6PD deficiency is when someone doesn't have enough of the enzyme G6PD, which protects red blood cells) as this can lead to a condition where the body does not have enough red blood cells.
- If you develop any skin adverse reaction, such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE), treatment with ASPEN PARACETAMOL 1 g IV must immediately be discontinued. These reactions can be life-threatening and are

characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain. Your health care provider must immediately discontinued treatment with ASPEN PARACETAMOL 1 g IV, if you experience any of these symptoms.

- if you take salicylates like aspirin. If taken together with ASPEN PARACETAMOL 1 g IV, it increases the risk of kidney diseases.
- if you are taking blood thinning medicines, such as warfarin.

Children

The safety and efficacy of ASPEN PARACETAMOL 1 g IV in children weighing less than 33 kg (approximately 11 years old) has not been established.

Other medicines and ASPEN PARACETAMOL 1 g IV

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

Tell your doctor if you are taking any of the following:

- Probenecid: used in the treatment of gout. May influence the excretion of ASPEN PARACETAMOL 1 g IV.
- Barbiturates (e.g. primidone): used to control seizures. May decrease the effects of ASPEN PARACETAMOL 1 g IV.
- Alcohol (chronic or excessive use): May increase the risk of liver toxicity
- Anticoagulants (e.g. coumarin such as warfarin): medicines used to thin your blood. May increase the risk of bleeding.
- Salicylamide: used for pain and fever. May prolong the removal of paracetamol from your body.

- Salicylates (e.g., aspirin): medicines used for pain, fever and inflammation. May increase the risk of kidney diseases.
- Phenytoin, carbamazepine (medicines used for seizures (fits)), rifampicin, isoniazic (used to treat TB), zidovudine (used to treat HIV) amoxicillin and clavulanic acid (antibiotic). May increase the risk of liver toxicity.
- Metoclopramide: used to treat nausea and vomiting. May cause ASPEN PARACETAMOL 1 g IV to work quicker.
- Flucloxacillin: used to treat bacterial infections. May cause build up of acid in your body.

ASPEN PARACETAMOL 1g IV contains paracetamol and this must be taken into account if other medicines containing paracetamol or propacetamol are taken, in order not to exceed the recommended daily dose (see section How ASPEN PARACETAMOL 1g IV will be administered to you).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving ASPEN PARACETAMOL 1 g IV.

Driving and using machines

ASPEN PARACETAMOL 1g IV should not affect your ability to drive and use machinery. ASPEN PARACETAMOL 1g IV will be administered to you in a hospital setting whilst under the supervision of a medical doctor.

3. How ASPEN PARACETAMOL 1 g IV will be administered to you

You will not be expected to give yourself ASPEN PARACETAMOL 1 g IV. It will be given to you by a doctor or nurse through a drip into a vein (intravenous infusion).

This will take about 15 minutes.

You will be closely monitored during the infusion.

ASPEN PARACETAMOL 1G IV is restricted to use in patients weighing more than 33 kg.

Your doctor will determine the correct dose for you according to your body weight.

DO NOT EXCEED THE RECOMMENDED DOSE

Your doctor will tell you how long your treatment with ASPEN PARACETAMOL 1g IV will last. If you have the impression that the effect of ASPEN PARACETAMOL 1g IV is too strong or too weak, tell your doctor.

If you are given more ASPEN PARACETAMOL 1g IV than recommended

Since a healthcare provider will administer ASPEN PARACETAMOL 1g IV, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

In overdose cases, symptoms generally appear within the first 24 hours and comprise of: nausea, vomiting, loss of appetite, pale colour of the skin and stomach pain.

If you think you may have been given an overdose, tell a doctor immediately due to the risk of irreversible liver damage.

If you forget to receive ASPEN PARACETAMOL 1g IV

Since a healthcare provider will administer ASPEN PARACETAMOL 1g IV, it is unlikely that the dose will be missed.

4. Possible side effects

ASPEN PARACETAMOL 1g IV can have side effects.

Not all side effects reported for ASPEN PARACETAMOL 1g IV are included in this leaflet. Should your general health worsen or if you experience any untoward effects while ASPEN PARACETAMOL 1g IV is being administered to you, please consult your healthcare provider for advice.

If any of the following happens, stop receiving ASPEN PARACETAMOL 1g IV and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), severe cutaneous adverse reactions (SCARS) such as toxic epidermal necrolysis (TEN), acute generalised exanthematous pustulosis (AGEP), eosinophilia and systemic (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE).

These are all very serious side effects. If you have them, you may have had a serious reaction to ASPEN PARACETAMOL 1g IV. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Decreased blood platelets which results in easy bruising, including abnormal bleeding from nose and/or gums, the presence of blood in the urine or stool and cuts that continue bleeding (thrombocytopenia), decrease in the number of red and white blood cells (pancytopenia),
- fever and chills, faster heart rate and breathing, muscle weakness and extreme tiredness, sore throat, swollen and bleeding gums; these are signs that your white blood cell levels are lower than normal (agranulocytosis, neutropenia, leukopenia),
- reduced oxygen in the blood with symptoms such as tiredness, weakness, shortness of breath, irregular heartbeat, dizziness or lightheadedness, chest pain and cold hands and feet (anaemia),
- inflammation of the pancreas (pancreatitis),
- inflammation of the liver (hepatitis), liver failure (inability of the liver to perform its normal functions), liver cells death (hepatic necrosis),
- kidney failure.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Low blood pressure (hypotension), sudden reddening of the face, neck, or upper chest (flushing),
- increased levels of liver enzymes,

- abdominal pain commonly caused by kidney stones (renal colic), presence of white blood cells in urine without an infection (sterile pyuria),
- general feeling of discomfort or uneasiness (malaise).

Side effects with an unknown frequency:

- Nausea, vomiting,
- inflammation of the skin (dermatitis), redness of the skin (erythema), red, sometimes itchy bumps on the skin (urticaria),
- fast beating heart rate (tachycardia),
- administration site reactions.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA**: via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of ASPEN PARACETAMOL 1 g IV.

5. How to store ASPEN PARACETAMOL 1 g IV

Store at or below 30 °C.

Do not refrigerate or freeze.

Do not use after the expiry date stated on the label.

Store all medicines out of reach of children.

Do not store in a bathroom.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

Keep the vial(s) in the outer carton in order to protect from light.

Once opened, the vial should be used immediately.

Any unused portion should be discarded.

6. Contents of the pack and other information

What ASPEN PARACETAMOL 1 g IV contains

The active substance is 1 g of paracetamol.

The other ingredients are cysteine chlorhydrate monohydrate, disodium phosphate dihydrate, hydrochloric acid (for pH adjustment), mannitol, sodium hydroxide (for pH adjustment) and water for injection.

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

Sugar free

What ASPEN PARACETAMOL 1 g IV looks like and contents of the pack

ASPEN PARACETAMOL 1g IV solution for infusion is clear and slightly yellowish.



ASPEN PARACETAMOL 1g IV is available in 100 ml clear glass vials [closed with bromobutyl stoppers and sealed with aluminium caps], in pack sizes of 1 vial and 10 vials, respectively.

Not all pack sizes may be marketed

Holder of Certificate of Registration

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This leaflet was last revised in

22 February 2024

Registration number

45/2.7/0374

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information

Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088



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