

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

CETAGESIC IV PAED, 10 mg/mL solution for infusion

Paracetamol

Sugar free

Read all of this leaflet carefully before you are given CETAGESIC IV PAED

- 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.
- CETAGESIC IV PAED 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 is in this leaflet

1. What CETAGESIC IV PAED is and what it is used for
2. What you need to know before your child is given CETAGESIC IV PAED
3. How to use CETAGESIC IV PAED
4. Possible side effects
5. How to store CETAGESIC IV PAED
6. Contents of the pack and other information

1. What CETAGESIC IV PAED is and what it is used for

The name of your medicine is CETAGESIC IV PAED. CETAGESIC IV PAED contains a medicine called Paracetamol. This belongs to a group of medicines called analgesics and antipyretics.

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Paracetamol has analgesic and antipyretic activities.

Specific indications include:

CETAGESIC IV PAED is an analgesic (it relieves pain), so it is used in children 1 year of age and older for the short-term treatment of mild to moderate pain, especially following minor surgery and the short-term treatment of fever where the oral route is unsuitable.

2. What you need to know before your child is given CETAGESIC IV PAED

CETAGESIC IV PAED should not be administered to your child:

If your child is hypersensitive (allergic) to paracetamol, or any of the other ingredients

If your child has severe liver disease including alcoholic hepatitis

Do not let your child have this medicine if any of the above applies to your child. If you are not sure, talk to your doctor, nurse or pharmacist before your child is given CETAGESIC IV PAED.

Warnings and Precautions

Special care should be taken with CETAGESIC IV PAED:

If your child has liver or kidney disease, or alcohol abuse,

If your child is taking other medicines containing paracetamol including prescription and non-prescription medicines,

If your child has serious skin reaction or allergic reaction,

If your child has nutritional problems (malnutrition) or dehydration,

If your child is taking or have recently taken medication, especially probenecid, salicylamide or enzyme-inducing substances,

If your child has Glucose 6 Phosphate Dehydrogenase (G6PD) deficiency which is an error of metabolism that predisposes to red blood cell breakdown, which may lead to haemolytic anaemia,

If you are pregnant or breastfeeding,

CETAGESIC IV PAED is considered high in sodium. This should be particularly taken into account

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for those on a low salt diet

CETAGESIC IV PAED contains 8,0 mg propylene glycol in each mL, which is equivalent to 12 mg/kg per 1,5 mL (total daily dose for patients > 10 kg and ≤ 33 kg is 48 mg/kg propylene glycol).

Other medicines and CETAGESIC IV PAED

Please tell your doctor or pharmacist if your child is taking, have recently taken or might take any other medicines. This is because CETAGESIC IV PAED can affect the way some other medicines work. Also, some medicines can affect the way that CETAGESIC IV PAED works.

In particular, tell your doctor if you are taking any of the following 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. Inform your doctor if your child is taking other medicines containing paracetamol.
- A dose reduction should be considered for concomitant treatment with probenecid.
- Patients receiving phenytoin therapy should avoid large and/ or chronic doses of paracetamol. Patients should be monitored for evidence of hepatotoxicity
- Caution is advised when paracetamol is administered concomitantly with antibiotic called as flucloxacillin due to the increased risk of metabolic acidosis.
- Please inform your doctor or pharmacist if your child is taking oral anticoagulants. Closer check-ups of the effect of the anticoagulant might be necessary.

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.

Driving and using machines

No relevant effect observed on driving and using machines.

3. How to use CETAGESIC IV PAED

How CETAGESIC IV PAED is given

The paracetamol solution is administered as an intravenous (into a vein) infusion over 15 minutes.

How much CETAGESIC IV PAED is given

DO NOT EXCEED THE RECOMMENDED DOSE.

You will not be expected to give yourself CETAGESIC IV PAED. 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. The maximum daily dose must not exceed 60 mg/kg.

Use in patients with kidney problem

Your doctor will decide what dose to give you based on a blood test.

Use in patients with liver problem

Your doctor will reduce the dose or prolong dosing interval.

If you forget to use CETAGESIC IV PAED

Since a healthcare professional will administer this medicine, it is unlikely that you will not be given the medicine as it has been prescribed. However, if you do think you have missed a dose, tell your healthcare professional.

If you receive more CETAGESIC IV PAED than you should.

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

However, in the event of overdosage your doctor will manage the overdosage, immediately. This is because too much paracetamol can cause serious liver damage.

4. Possible side effects

CETAGESIC IV PAED can have side effects.

Not all side effects reported for CETAGESIC IV PAED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor straight away if you notice any of the following serious side effects. Your doctor will stop CETAGESIC IV PAED immediately:

Less Frequent

- Malaise
- A serious skin reaction or allergic reaction, stop the treatment immediately and inform your doctor
- 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.
- 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.
- Renal colic (pain due to a stone in the urinary tract), kidney failure

Not known: frequency cannot be estimated from the available data

- Redness of the skin, flushing, itching, decrease in platelets, nausea, vomiting, liver failure, allergic reaction, serious skin reactions and abnormally rapid beating of the heart, have been reported.

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- 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions 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>

5. How to store CETAGESIC IV PAED

Keep this medicine out of the sight and reach of children.

Store at or below 30 °C. Protect from light. Do not refrigerate or freeze.

Once opened, the vial should be used immediately.

Discard any unused portion.

Do not administer if visible particles are present.

6. Contents of the pack and other information

What CETAGESIC IV PAED contains

Each ml contains paracetamol 10 mg

Sugar Free

The other ingredients are

Propylene glycol,

Citric Acid Monohydrate,

Sodium Metabisulphite,

Disodium Hydrogen Phosphate Dihydrate,

Sodium Chloride,

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Water for Injection.

What CETAGESIC IV PAED looks like and contents of the pack

50 mL clear glass vials USP type I, closing with 32 mm bromobutyl rubber stoppers and sealed with 33 mm aluminium flip off seals.

HOLDER OF CERTIFICATE OF REGISTRATION

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This leaflet was last revised in

28 September 2023

REGISTRATION NUMBER

52/2.7/0445