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1.5.3 Patient Information Leaflet (PIL)

Package leaflet: Information for the patient

IXINE, film-coated tablet 200 mg
IXINE, Kid, powder for oral suspension 100 mg/5 ml
IXINE 1st age, powder for oral suspension 40 mg/5 ml
Cefixime

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What IXINE is and what it is used for
2. What you need to know before you take IXINE
3. How to take IXINE
4. Possible side effects
5. How to store IXINE
6. Contents of the pack and other information

1. What IXINE is and what it is used for

This medicine is an antibiotic of the betalactams family, from the group of the third-generation cephalosporins, close to the group of the penicillins.

This medicine is indicated for:

- Certain infections of the uro-genital tract
- Acute otitis, sinusitis
- Bronchial and pulmonary infections

2. What you need to know before you take IXINE

Do not take IXINE:

- If you or your child are allergic to cefixime or any of the other ingredients of this medicine (listed in section 6).
- If you or your child are allergic to another antibiotic of the betalactams family.

Warnings and precautions

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Talk to your doctor or pharmacist before taking IXINE.

Before you take IXINE you should tell your doctor:

- If you or your children already had an allergy caused by an antibiotic treatment. You or your child may also be allergic to this treatment.
- If you or your child have a kidney disease. Your doctor will need to adapt the daily dose of your treatment.
- If you or your child already had a haemolytic anaemia following a treatment with an antibiotic of the family of the cephalosporins, including IXINE (decrease of red blood cells that may cause pallor, weakness or breathlessness).

During or after the treatment, immediately tell your doctor:

- If you or your child has diarrhoea. Do not take or give your child any treatment against diarrhoea without medical advice.
- If you or your child have spots or itchy rashes.
- If you or your child have a bullous type of severe skin reaction with detachment of the skin that can rapidly spread to the whole body and put you or your child in danger (Lyell syndrome, Stevens-Johnson syndrome) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

As for all medicines belonging to this class of antibiotics (betalactams), the administration of this medicine, might result in a risk of encephalopathy that might cause convulsions, confusion, conscience disorders, particularly in case of overdose or in case of altered kidney function. If such disorders appear, immediately consult your doctor or pharmacist (see sections 3 and 4).

Your doctor might decide to stop this treatment and/or prescribe an adapted treatment (see section 4 “Possible side effects”).

In case of laboratory tests

IXINE might distort:

- The dosage of ketones in urine.
- The dosage of glucose in urine.
- The diagnosis test for certain blood diseases.

Other medicines and IXINE

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

IXINE with food and drink

No object.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

This medicine will be used during pregnancy only under medical advice.

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If you find out that you are pregnant during the treatment, tell your doctor, he will determine the necessity of continuing your treatment.

Breast-feeding

Breast-feeding is possible during the treatment with this medicine. However, if digestive disorder (diarrhoea, fungi infection) or spots appear in your child, stop breast-feeding or stop the treatment and seek medical advice.

Driving and using machines

This medicine can impact the ability to drive or use machinery notably because of the possible appearance of dizziness or encephalopathy (that may cause convulsions, confusion, conscience disorders or abnormal movements) (see sections 3 and 4).

IXINE tablet contains lactose

If you have been told by your doctor that you or your child have an intolerance to some sugars, contact your doctor before taking this medicinal product.

IXINE Kid and IXINE 1st age contain sucrose

If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking or giving this medicinal product to your child.

IXINE Kid and IXINE 1st age contain tartrazine

May cause allergic reactions.

IXINE Kid and IXINE 1st age contain sodium benzoate

3. How to take IXINE

Posology

The presentation IXINE Tablet 200 mg is recommended in children over 12 years of age and in adults.

The presentation IXINE Kid is recommended in children from 30 months to 12 years of age. The presentation IXINE 1st age 40 mg/5 ml is recommended in infants from 6 to 30 months of age.

Adults

As an indication, the usual posology is two 200 mg tablets per day.

Children

As an indication, the usual posology is children over 6 months of age is 8 mg per kg and per day, in 2 administrations, with a 12-hour spacing.

The dose per administration is indicated in unit of volume on the measuring cap.

Two daily administrations are required.

For instance, for a child weighing 10 kg, 5 ml of IXINE 1st age would be given, twice a day. A child of 50 kg would take 10 ml of IXINE kid, also twice a day.

Method of administration

Oral route.

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The oral suspension is to be reconstituted by adding water up to the mark to make up a total volume of 40 ml and to shake before use.

If you or your child take more IXINE than you should

As for all the medicines belonging to this class of antibiotics (betalactams), the administration of this medicine, especially in case of overdose, might cause a risk of encephalopathy that can result in convulsions, confusion, conscience disorders, or abnormal movements. If such disorders occur, consult immediately your doctor or your pharmacist (see section 2 and 4).

If you or your child forget to take IXINE

Do not take a double dose to make up for a forgotten dose.

If you or your child stop taking IXINE

To be efficient, this antibiotic should be used regularly at the prescribed doses, and as long as your doctor has instructed you to.

If the fever or any other symptoms fades away, this does not mean that you or your child are completely healed.

The potential impression of tiredness is not caused by the treatment but to the infection itself. Reducing or stopping the treatment would have no effect on that impression and would delay healing.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should contact your doctor immediately if the following undesirable effects appear:

- Diarrhoea:

If a diarrhoea appears during or after the administration of medicines, you should not try to treat yourself or your child. You should immediately contact your doctor. He might decide to stop this treatment and prescribe an adapted treatment.

The risk diarrhoea is frequent. The diarrhoea can be bloody, in very rare cases, it can be caused by a serious form of colitis (pseudo membranous colitis or enterocolitis) requiring to stop the treatment.

- Allergy: this medicine can cause an allergic reaction as urticaria or more rarely an angioedema (sudden swelling of the neck and face that can result in breathing difficulty). If one of the effect appear, stop the treatment and contact your doctor immediately.

Other possible undesirable effects:

- Effects on the digestive tract: nausea, vomiting, difficulty digesting, stomach pains.

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- Effect on the skin: very rare bullous eruption with skin detachment that can rapidly spread to the whole body and put the patient in danger (Lyell syndrome, Stevens-Johnson syndrome), skin eruption with skin blistering that can impact the mouth (erythema multiform) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). In that case, stop the treatment and seek the advice of your doctor.
- Effects on the kidneys: kidney disease (kidney failure by interstitial nephritis).
- Effects of the nerves and brain: rarely, headaches and dizziness.

Convulsions were also reported with cephalosporins, including cefixime (undetermined frequency).

Serious neurological disorders called encephalopathies that cause convulsions, confusion, conscience disorders and abnormal movements, particularly in case of overdose or of altered kidney function (see sections 2 and 3).

- Visible effects on the results of a blood test:
- Rarely, increase in transaminases and alkaline phosphatases (liver enzymes).
- Rarely, increase in blood creatinine (measure of the kidney function) and urea.
- Miscellaneous anomalies of blood numeration formula: increase in certain white blood cells (eosinophils), increase or decrease in blood platelets and decrease in white blood cells that can cause serious infections and fever (leucopenia), decrease in red blood cells (anaemia) caused by the destruction of red blood cells.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

5. How to store IXINE

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

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

The reconstituted suspensions of IXINE kid and IXINE first age can be stored at room temperature for 7 days.

6. Contents of the pack and other information

What IXINE contains

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- The active substance is cefixime

IXINE tablet

- The other ingredients are lactose, microcrystalline cellulose, talc, magnesium stearate, sodium croscarmellose, hypromellose, titanium dioxide (E171), macrogol 6000, povidone K30.

IXINE Kid and IXINE 1st age

- The other ingredients are: colloidal anhydrous silica, sodium benzoate (E211), xanthan gum, strawberry essence, tartrazine yellow (E102), sucrose.

What IXINE looks like and contents of the pack

IXINE tablet: Aluminium/aluminium blister containing 10 film-coated tablets.

IXINE Kid and IXINE 1st age: 40 ml plastic bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Product license holder

Expfar sa, Avenue Thomas Edison 105 - 1402 Thines, BELGIUM

Manufacturer

Gracure Pharmaceuticals Ltd.,

E-1105, Industrial Area, Phase-III, Bhiwadi, Dist. Alwar (Raj.) INDIA

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