

**PACKAGE LEAFLET:  
INFORMATION FOR THE USER**

## **Suprax 100mg/5mL Powder for Paediatric Oral Suspension**

### **Cefixime**

Is this leaflet hard to see or read?

Phone 01403 5600 for help

**Read all of this leaflet carefully before giving your child 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 child's doctor or your pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or your pharmacist.

**In this leaflet:**

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

## **1. What Suprax Paediatric is and what it is used for.**

Suprax Paediatric 100mg/5ml Powder for Oral Suspension (called Suprax Paediatric in this leaflet) contains a medicine called cefixime. This belongs to a group of antibiotics called 'cephalosporins'.

Suprax Paediatric is specially made for children.

The bottle contains powder which has been mixed with water by your pharmacist. The suspension is strawberry flavoured and is ready to use.

Suprax is used to treat infections caused by bacteria. These include treating infections in the upper respiratory tract and also in the urinary tract.

## **2. What you need to know before you give Suprax Paediatric to your child.**

**Do not give this medicine to your child and tell their doctor if:**

X Your child is allergic (hypersensitive) to cefixime, any other cephalosporin antibiotics including penicillin or to any of the other ingredients of this medicine (see Section 6: Further information).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat and tongue.

Do not give this medicine to your child if the above applies to them. If you are not sure, talk to your child's doctor or your pharmacist before giving Suprax.

### **Warnings and precautions**

**Take special care with Suprax Paediatric**

**Check with your child's doctor or your pharmacist before giving this medicine if your child:**

- ▲ Has ever had colitis
- ▲ Has allergic tendencies such as asthma, rash or hives
- ▲ Has severe kidney problems
- ▲ Is under 6 months, as the safety for use has not been established in this group.

If you are not sure if any of the above apply to your child, talk to your doctor or pharmacist before giving this medicine.

Medicines such as Suprax, make you more susceptible to a condition called "encephalopathy". You may have sudden involuntary muscle contractions, dizziness, feel less alert or begin to lose consciousness (see section 4).

### **Other medicines and Suprax Paediatric**

Please tell your child's doctor or your pharmacist if your child is taking or has recently taken any other medicines.

This includes medicines you buy without a prescription, including herbal medicines. This is because Suprax Paediatric can affect the way some other medicines work. Also some medicines can affect the way Suprax Paediatric works.

In particular, tell your child's doctor if they are taking:

- Medicines to thin the blood such as warfarin

#### **Pregnancy and breast-feeding**

This medicine is specially made for children. However, if you are taking this medicine as an adult, you should talk to your doctor before taking this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding or planning to breast feed

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

#### **Driving and using machines**

This medicine is specially made for children. However, if you are taking this medicine as an adult, you may start to move abnormally, suffer from sudden involuntary muscle contractions, dizziness or feel less alert. If this happens, do not drive or use any tools or machines.

#### **Tests**

If your child requires any tests (such as blood or urine tests) while taking this medicine, please make sure your child's doctor knows that your child is taking Suprax Paediatric.

#### **Important information about some of the ingredients of Suprax Paediatric**

Suprax Paediatric contains:

- **Sucrose:** This is a type of sugar. If you have been told by your child's doctor that they cannot tolerate or digest some sugars talk to your child's doctor before giving them this medicine.

## **3. How to give Suprax Paediatric to your child.**

#### **Having this medicine**

Always use Suprax Paediatric exactly as your child's doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The amount of medicine given will depend on the weight and age of your child

- Give this medicine to your child by mouth
- Suprax comes with a measuring spoon that can measure 3.75ml to 5ml. Use this spoon to give your child the medicine
- The dose can be given in one go or the dose can be divided into two and given at different times
- If you feel the effect of the medicine is too weak or too strong, do not change the dose yourself, but ask your child's doctor
- Shake the bottle well before use and make sure the bottle is tightly closed after use

Carefully read the label from the pharmacist. Ask your pharmacist if you are not sure about the dose to give. The medicine should be taken for the prescribed number of days.

#### **How much to give**

The usual dose is:

##### **Adults, Elderly and Children over 12 years or weighing more than 50kg**

- 10ml to 20ml each day, depending on the infection
- This may be given once daily or as two divided doses.

##### **Children 9 to 12 years old**

- 15ml each day
- This may be given once daily or as two divided doses.

##### **Children aged 5 to 8 years**

- 10ml each day
- This may be given once daily or as two divided doses.

##### **Children 2 to 4 years old**

- 5ml each day
- This may be given once daily or as two divided doses.

##### **Children 6 months to 2 years old**

- 0.4ml/kg each day (equivalent to 8mg/kg)
- This may be given once daily or as two divided doses.

#### **People with kidney problems**

- Your doctor may prescribe a lower dose

#### **If your child has more Suprax Paediatric than they should**

If your child has too much of this medicine, talk to your child's doctor straight away.

They may have symptoms of encephalopathy - moving abnormally, sudden involuntary muscle contractions, dizziness or feeling less alert.

#### **If you forget to give Suprax Paediatric to your child**

If you forget to give your child a dose, give it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not give a double dose to make up for a forgotten dose.

#### **If you stop giving Suprax Paediatric to your child**

Do not stop giving your child the medicine without talking to your doctor. Your child should not stop taking Suprax just because he or she feels better. This is because the infection may come back or get worse again.

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

## **4. Possible side effects**

Like all medicines, Suprax Paediatric can cause side effects, although not everybody gets them.

#### **Tell your doctor straight away or go to the nearest hospital casualty department if you notice any of the following serious side effects – your child may need urgent medical treatment:**

- If your child has an allergic reaction. The signs may include: a rash, joint pain, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- Severe allergic reaction including blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals or layers of skin peeling off. Also flu-like symptoms, aching muscles and fever. These may be a sign of serious allergies called 'Stevens-Johnson syndrome', 'toxic epidermal necrolysis', "serum sickness like reaction", white blood cell disorder (eosinophilia) or 'drug rash with white blood cell disorder (eosinophilia) and systemic symptoms (DRESS)'
- If your child gets a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called 'erythema multiforme'
- If your child get infections more easily than usual. This could be because of a blood disorder. This normally gets better after stopping the medicine
- If your child bruises or bleeds more easily than normal. This could be because of a blood disorder. This normally gets better after stopping the medicine
- If your child gets nose bleeds, bleeding gums, chills, tiredness, pale skin (often with a yellow tinge), shortness of breath. This may be due to haemolytic anaemia
- Your child may have sudden involuntary muscle contractions, dizziness, feel less alert or begin to lose consciousness. This is called "encephalopathy"

#### **Stop giving your child this medicine and contact the child's doctor without delay if they get:**

- Severe watery diarrhoea that will not stop and your child is feeling weak and has a fever. This may be something called 'Pseudomembranous colitis'.

#### **Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days**

- Feeling sick (nausea) or being sick (vomiting)
- Stomach pains, indigestion or wind
- Headaches
- Feeling dizzy
- Feeling itchy in the genital or vaginal area
- Facial swelling
- Fever
- Shortness of breath
- Yellowing of the skin
- Fits (convulsions) - Frequency not known

#### **Tell your child's doctor if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet**

#### **Blood tests**

Suprax Paediatric can cause blood clots or changes to the way the liver and kidney work (kidney failure is rare). This would be shown up in blood tests. This is not common and goes back to normal after stopping this medicine.

If you think your child is reacting badly to the medicine or having any problems, then discuss it with the child's doctor or your pharmacist.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to Store Suprax Paediatric

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

After the powder has been mixed with water by the pharmacist, keep the bottles of medicine at room temperature.

#### **Do not freeze.**

After being mixed with water, Suprax Paediatric can be used for 14 days. Any liquid remaining after 14 days should be returned to your pharmacist.

Do not use this medicine after the expiry date which is stated on the bottle.

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 to protect the environment.

## 6. Contents of the pack and other Information

#### **What Suprax 100mg/5mL Powder for Paediatric Oral Suspension contains**

- Each 5ml spoonful of liquid contains 100mg of the active substance cefixime
- The other ingredients are sucrose, xantham gum, sodium benzoate and strawberry flavour containing Maltodextrin, Acacia Gum, Propylene glycol, Glyceryl triacetate and Maltol.

#### **What Suprax Paediatric looks like and contents of the pack**

Suprax Paediatric is available in 5 ml (sample pack), 37.5 ml, 50 ml, 75ml and 100ml bottles and comes with a measuring spoon that can measure 3.75ml to 5ml. Not all pack sizes may be marketed.

The bottle contains powder which will have been mixed with water by your pharmacist, to form a strawberry flavour medicine ready for use.

#### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

Sanofi-aventis Ireland Limited, , T/A SANOFI

Citywest Business Campus, Dublin 24

Tel: 0 1403 5600 Fax: 01 403 5687

email: [IEmedinfo@sanofi.com](mailto:IEmedinfo@sanofi.com)

Manufacturer

Merck Farma y Quimica, S.A. Poligono Merck,

08100 Mollet del Valles (Barcelona), Spain.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

**This leaflet was last revised in 07/2017**

©Sanofi-aventis, 2017