

PATIENT INFORMATION LEAFLET
(PIL)

**PATIENT INFORMATION LEAFLET:
INFORMATION FOR THE USER
SKYCLAV 457**

Amoxicillin 400 mg/clavulanic acid 57 mg

Read all of this leaflet carefully before you start giving your child this medicine because it contains important information for them.

- 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 your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours child.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider

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1. What Skyclav is and what it is used for

Skyclav is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called “penicillins” that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

Skyclav is used in babies and children to treat the following infections:

- middle ear and sinus infections
- respiratory tract infections
- urinary tract infections
- skin and soft tissue infections including dental infections
- bone and joint infections.

2. What you need to know before you give Skyclav

Do not take Skyclav :

- if they are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6).
- if they have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.
- if they have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

➔ **Do not take Skyclav if any of the above apply to you.** If you are not sure, talk to your doctor or pharmacist before taking Skyclav .

Warnings and Precautions

Talk to their doctor or pharmacist before giving Skyclav to your child if they:

- have glandular fever
- are being treated for liver or kidney problems

- are not passing water regularly.

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

In some cases, their doctor may investigate the type of bacteria that is causing your child's infection. Depending on the results, your child may be given a different strength of Skyclav or a different medicine.

Conditions you need to look out for

Skyclav can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while your child is taking Skyclav, to reduce the risk of any problems. See 'Conditions you need to look out for' in section 4.

Blood and urine tests

If your child is having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that they are taking Skyclav. This is because Skyclav can affect the results of these types of tests.

Other medicines and Skyclav

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines.

- If your child is taking allopurinol (used for gout) with Skyclav, it may be more likely that they will have an allergic skin reaction.
- If your child is taking probenecid (used for gout), your doctor may decide to adjust the dose of Skyclav.
- If medicines to help stop blood clots (such as warfarin) are taken with Skyclav then extra blood tests may be needed.
- Skyclav can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
- Skyclav can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

Driving and using machines

Skyclav can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

3. How to take Skyclav

Always give this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children weighing 40 kg and over

- This suspension is not usually recommended for adults and children weighing 40 kg and over. Ask your doctor or pharmacist for advice.

Children weighing less than 40 kg

All doses are worked out depending on the child's body weight in kilograms.

- Your doctor will advise you how much Skyclav you should give to your baby or child.
- Recommended dose - 25 mg/3.6 mg to 45 mg/6.4 mg for each kilogram of body weight a day, given in two divided doses.
- Higher dose - up to 70 mg/10 mg for each kilogram of body weight a day, given in two divided doses.

Patients with kidney and liver problems

- If your child has kidney problems the dose might be lowered. A different strength or a different medicine may be chosen by your doctor.
- If your child has liver problems they may have more frequent blood tests to see how their liver is working.

How to give Skyclav

- SKYCLAV should be administered with a meal to minimise potential gastrointestinal intolerance.
- Tap the bottle to loosen the Powder. Slowly add pre-boiled, cold water upto the arrow mark on the label. Shake vigorously.
- Adjust the volume up to the arrow mark on the label adding more water, if necessary. This makes 70 ml of the suspension.
- Store the reconstituted suspension in refrigerator when not in use.
- Use the reconstituted suspension within 7 days.
- Shake well before use

If you give more Skyclav than you should

If you give your child too much Skyclav, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to their doctor as soon as possible. Take the medicine bottle to show the doctor.

If you forget to give Skyclav

If you forget to give your child a dose, give it as soon as you remember. You should not give your child the next dose too soon, but wait about 4 hours before giving the next dose. Do not take a double dose to make up for a forgotten dose.

If your child stop taking Skyclav

Keep giving your child Skyclav until the treatment is finished, even if they feel better. Your child needs every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

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. The side effects below may happen with this medicine.

Conditions you need to look out for

Allergic reactions:

- skin rash
- inflammation of blood vessels (*vasculitis*) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- fever, joint pain, swollen glands in the neck, armpit or groin

- swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing
- collapse.

➔ **Contact a doctor immediately** if you get any of these symptoms. **Stop taking Skyclav.**

Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

➔ **Contact your doctor as soon as possible** for advice if you get these symptoms.

Very common side effects

These may affect more than 1 in 10 people

- diarrhoea (in adults).

Common side effects

These may affect up to 1 in 10 people

- thrush (*candida* - a yeast infection of the vagina, mouth or skin folds)
 - feeling sick (nausea), especially when taking high doses
- ➔ if affected take Skyclav before food
- vomiting
 - diarrhoea (in children).

Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised itchy rash (*hives*)
- indigestion
- dizziness
- headache.

Uncommon side effects that may show up in your blood tests:

- increase in some substances (*enzymes*) produced by the liver.

Rare side effects

These may affect up to 1 in 1000 people

- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – *erythema multiforme*)
- ➔ if you notice any of these symptoms contact a doctor urgently.

Rare side effects that may show up in your blood tests:

- low number of cells involved in blood clotting
- low number of white blood cells.

Frequency not known

Frequency cannot be estimated from the available data.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the protective membrane surrounding the brain (*aseptic meningitis*)
- Serious skin reactions:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface – *toxic epidermal necrolysis*)
 - widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)
 - a red, scaly rash with bumps under the skin and blisters (*exanthemous pustulosis*).

➔ **Contact a doctor immediately if you get any of these symptoms.**

- inflammation of the liver (*hepatitis*)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of Skyclav or who have kidney problems)
- black tongue which looks hairy

Side effects that may show up in your blood or urine tests:

- severe reduction in the number of white blood cells
- low number of red blood cells (*haemolytic anaemia*)
- crystals in urine.

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 Email: regulatory@eskaypharma.com By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Skyclav

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.

Store in a cool, dry place. Protect from light. Store between 15° C-25° C

After reconstitution

Store the suspension in a refrigerator (2°C - 8°C). Do not freeze. the suspension should be used within 7 days.

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

6. Contents of the pack and other information

What Skyclav contains

- The active substances are amoxicillin and clavulanic acid. After reconstitution Each 5 ml contains amoxicillin trihydrate equivalent to 400 mg amoxicillin and potassium clavulanate equivalent to 57 mg of clavulanic acid.
The other ingredients are: Mannitol, Sodium citrate, Citric Acid Monohydrate, Sodium Benzoate, Xanthan Gum, Colloidal Silicon Dioxide, Aspartame, Flavour Capsil cloudifying, Flavour strawberry

What Skyclav looks like and contents of the pack

A white to creamish granular powder filled in 70 ml HDPE Plastic bottle, after reconstitution with water it gives creamish coloured homogenous suspension with Strawberry Flavour.

They are packaged in:

- 70 ml HDPE Plastic Bottle packed in a carton with leaflet & measuring cup.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

ESKAY THERAPEUTICS LTD, 42, SOUTH INDUSTRIAL AREA, ACCRA, GHANA

Manufacturer:

SPARSH BIO-TECH PVT. LTD., PLOT No. 1; SURVEY No. 242/243/244, LAKHABAVAD,
JAMNAGAR-361 006, INDIA.

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