

UNASYN[®] TABLET

Sultamicillin (375 mg)

What is in this leaflet

1. What UNASYN is used for
2. How UNASYN works
3. Before you use UNASYN
4. How to use UNASYN
5. While you are using UNASYN
6. Side Effects
7. Storage and Disposal of UNASYN
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What UNASYN is used for

UNASYN is indicated for infections caused by susceptible micro-organisms which include:

- upper respiratory tract infections including sinus infection, middle ear infection and tonsils inflammation
- lower respiratory tract infections including inflammation of the lungs and inflammation of the bronchial tubes
- kidneys and urinary tract infections
- skin and soft tissues infections
- gonococcal infections (a sexually transmitted disease)

UNASYN tablets may also be used in individuals who have been treated with injections of UNASYN and who have to further continue treatment with the same medicine by mouth.

How UNASYN works

UNASYN contains the active substance sultamicillin. Inside the body, sultamicillin is split into two substances, sulbactam and ampicillin. Together, these two substances are able to kill various types of bacteria.

Before you use UNASYN

- When you must not use it

Do not use UNASYN

- if you are allergic to sultamicillin or any penicillin, or any of the other ingredients of this medicine

Pregnancy and lactation

UNASYN crosses the placenta and reaches the foetus. If necessary, your doctor will assess the benefits of treatment with this medicine compared to the possible risks.

Do not take UNASYN if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell your doctor if you have:

- allergic reactions to penicillins, cephalosporins, carbapenems, beta lactams and other allergens
- any kidney or liver problems or if you develop any signs and symptoms of liver disease
- hereditary problems of galactose intolerance, the Lapp-lactase deficiency or glucose-galactose malabsorption
- a viral infection known as "infectious mononucleosis"
- any severe skin reactions
- severe and persistent diarrhoea, even as late as two or more months after taking the last dose

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, particularly any of the following:

- Allopurinol (medicines for gout)
- Anticoagulants (medicines that help to prevent blood clots)
- Antibacterial medicines (chloramphenicol, erythromycin, sulfonamides and tetracyclines)
- Estrogen-containing oral contraceptives
- Methotrexate (medicines used to treat cancer)
- Probenecid (medicines used to treat gout and hyperuricemia)

How to use UNASYN

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dosage for adults is 375-700 mg twice daily.

In the treatment of uncomplicated gonorrhoea, sultamicillin can be given as a single oral dose of 2.25 g.

The recommended dosage for children weighing less than 30 kg is 25-50 mg/kg/day in two divided doses.

For children weighing more than 30 kg, the usual adult dose should be given.

If you have severe kidney problems your doctor may extend dosing intervals.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

In both adults and children, treatment is usually continued until 48 hours after fever and other abnormal signs have resolved.

Treatment is normally given for 5-14 days, but the treatment period may be extended if necessary.

It is recommended to have at least 10 days of treatment for any infection caused by hemolytic streptococci (a type of bacteria).

Continue taking UNASYN for as long as your doctor recommends.

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- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause seizures.

While you are using it**- Things you must do**

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking UNASYN.

Tell your doctor immediately if you become pregnant while taking this medication.

Tell your doctor before undergoing any laboratory tests for glucose in urine as UNASYN can change the results.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give UNASYN to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of**Driving and using machines**

UNASYN is unlikely to affect your ability to drive or use machines. Do not drive or use machines if you feel dizzy after taking this medicine.

Side effects

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

Below are the common side effects experienced while taking UNASYN:

- Fungal infection caused by candida
- Headache
- Diarrhea
- Vomiting
- Stomach pain
- Nausea
- Rash
- Itching

UNASYN may cause severe allergy and serious skin reactions. Stop using UNASYN and seek medical assistance immediately if you experience any of the following symptoms:

- skin reddening, blisters, rash, fever, sore throat or eye irritation

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of UNASYN**- Storage**

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description**- What it looks like**

UNASYN is available as white, capsular-shaped, film-coated tablets for oral administration.

UNASYN can be found in 375 mg tablets, blister-pack of 20's and 100's.

Some product strengths or pack sizes may not be available in your market.

- Ingredients

- Active ingredient:
Sultamicillin

- Inactive ingredients:
Lactose, corn starch, sodium starch glycolate, hydroxypropylcellulose, magnesium stearate, hydroxypropylmethylcellulose 2910, titanium oxide, talc, macrogol 6000, purified water, carnauba wax, and specially denatured alcohol.

- MAL numbers:

MAL19910104ARZ

Manufacturer

Haupt Pharma Latina S.r.l.
Strada Statale 156 Dei Monti Lepini
Km 47,600,
Latina, 04100,
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Sultamicillin (375 mg)

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
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Avenue 5, Bangsar South,
No. 8 Jalan Kerinchi,
59200 Kuala Lumpur, Malaysia

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