

Package leaflet: information for the user

Clindamycin Sandoz® 150 mg, capsules

Clindamycin Sandoz® 300 mg, capsules

clindamycin hydrochloride monohydrate

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet:

1. What is Clindamycin Sandoz and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the pack and other information

1. What is Clindamycin Sandoz and what is it used for?

Clindamycin Sandoz is an antibiotic that inhibits the growth of certain types of bacteria and in some cases even kills them.

Clindamycin Sandoz can be used in the treatment of diseases caused by bacterial infections.

These include the following infections:

- pneumonia
- upper respiratory tract infections, including sore throat and sinusitis
- skin and soft tissue infections
- bone and joint infections
- infections of the female genital organs (gynecological infections). For these infections, Clindamycin Sandoz is given together with another antibiotic
- intra-abdominal infections, including peritonitis and abscesses in the abdomen. For these infections, Clindamycin Sandoz is given together with another antibiotic.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to lincomycin or to any of the substances in this medicine. You can find these substances in section 6.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before taking this medicine.

Conditions of importance when using Clindamycin Sandoz

- You have an intestinal inflammation or have had it in the past;
- Your liver or kidneys do not function properly;
- You regularly suffer from allergies.

It may be that your doctor decides that another medicine is more suitable for you.

Possible consequences of using Clindamycin Sandoz

The use of clindamycin can cause severe hypersensitivity reactions or severe skin reactions. You must contact your doctor immediately if you experience a skin disease characterized by the detachment of large areas of skin and mucous membranes (toxic epidermal necrolysis, Lyell's syndrome), severe allergic reaction with high fever, blisters on the skin, joint pain and/or eye inflammation (Stevens-Johnson syndrome), acute skin rash characterized by a sudden outbreak of pus-filled blisters with a red surrounding skin (acute generalized exanthematous pustulosis (AGEP)) or drug rash (DRESS). Treatment with clindamycin may need to be stopped.

Antibiotics, including clindamycin, can sometimes cause inflammation of the intestines. This is caused by a certain bacterium (*Clostridium difficile*) that can grow because other bacteria disappear due to the action of clindamycin (colitis or pseudomembranous colitis).

You must contact your doctor immediately if you experience diarrhea during treatment or within 3 weeks after treatment.

Sometimes the diarrhea can become very severe and there may also be mucus and blood in the stool (see also section 4 "Possible side effects").

Because clindamycin inhibits the growth of certain types of bacteria, the natural balance between these and other non-sensitive bacteria or microorganisms can be disturbed. This can lead to the growth of these organisms, particularly yeasts.

Clindamycin Sandoz capsules contain lactose. Patients with rare hereditary conditions such as galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not use this medicine.

Severe allergic reactions can occur, even immediately after the first dose. You should then immediately notify your doctor.

Sometimes treatment with Clindamycin Sandoz can be an alternative if you are allergic (hypersensitive) to penicillin. However, occasionally there may be an allergy (hypersensitivity) to Clindamycin Sandoz in individuals with an existing allergy to penicillin. You should take this into account if you are receiving Clindamycin Sandoz and are allergic to penicillin.

Acute kidney disorders may occur. Inform your doctor about all medications you are currently using and if you have existing kidney problems. Contact your doctor immediately if you experience reduced urination (decreased urine output), fluid retention which can lead to swelling of your legs, ankles, or feet, shortness of breath, or nausea.

Are you using any other medications?

Are you using any other medications besides Clindamycin Sandoz, or have you recently done so, or is there a possibility that you will use other medications in the near future? Then inform your doctor or pharmacist. This also applies to medications for which you do not need a prescription.

The effect of the following medications can be influenced by Clindamycin Sandoz:

- muscle relaxants used during surgeries; clindamycin can enhance the effect of these medications
- erythromycin, another antibiotic, because these medications reduce each other's effectiveness
- medications used to prevent blood clotting, such as warfarin. You may then bleed more easily. Your doctor will want to regularly check how well your blood can clot.

The following medication can reduce the effectiveness of Clindamycin Sandoz:

- Rifampicin (antibiotic against infections): rifampicin stimulates the activity of the enzymes responsible for the breakdown of Clindamycin Sandoz. This can reduce the effect of Clindamycin Sandoz.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

If you are pregnant or trying to become pregnant, Clindamycin Sandoz is only used if your doctor deems it strictly necessary.

Clindamycin Sandoz is excreted in breast milk and may potentially cause side effects on the intestinal flora of infants. When using Clindamycin Sandoz during breastfeeding, the benefits and risks should be carefully weighed, taking into account the importance of the treatment for the mother and the possible side effects of Clindamycin Sandoz on the infant. Your doctor will decide whether it is necessary to temporarily interrupt breastfeeding for the duration of the treatment with Clindamycin Sandoz.

Driving and using machines

No influence on driving ability or the use of machines has been observed.

Clindamycin Sandoz capsules contain lactose

The capsules contain lactose. If your doctor has informed you that you do not tolerate certain sugars, contact your doctor before taking this medicine.

3. How do you use this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Your doctor will determine the correct dosage and duration of treatment for you based on the severity of the infection and your weight.

The capsules should be taken with a full glass of water. This prevents the capsules from getting stuck in your esophagus, where they can cause inflammation. It is advisable to take the capsules at fixed times. You may take Clindamycin Sandoz during a meal, but this is not necessary.

Adults

The recommended dosage is 150-450 mg every 6 hours. For correct intake of the capsules, see above under section 3 "How do you take this medicine?".

Use in children

Children older than one month

Clindamycin in children should be dosed based on total body weight, regardless of obesity.

The recommended dosage is 8 – 25 mg per kg body weight per day divided into 3 or 4 equal doses.

The capsules should only be used by children who can swallow capsules. For correct intake of the capsules, see above under section 3 "How do you take this medicine?".

In addition, the use of capsules may be unsuitable to provide younger children with the precise dose.

Prolonged use of this medicine

If you need to take Clindamycin Sandoz for a long period, your doctor may perform regular blood and liver tests. Do not skip these check-ups by your doctor.

Have you taken too much of this medicine?

No specific toxic effects have been reported in case of an overdose.

If you have taken too much of this medicine, symptoms in the gastrointestinal tract (gastrointestinal symptoms) such as abdominal pain, inflammation of the esophagus, nausea, vomiting, and diarrhea may occur.

Contact your doctor or pharmacist immediately if you have taken too much Clindamycin Sandoz.

Did you forget to take this medicine?

You should simply continue with the next dose when you have missed a dose of Clindamycin Sandoz.

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

If you stop taking this medicine

Complete the entire Clindamycin Sandoz treatment as prescribed by your doctor.

Although you may notice improvement quite quickly in some cases, you should continue taking Clindamycin Sandoz. The infection may return if some harmful bacteria remain alive.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

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

Contact your doctor immediately if you experience:

- fluid retention which can lead to swelling of your legs, ankles, or feet, shortness of breath, or nausea.

Side effects occur at the following frequencies:

Common (occur in less than 1 in 10 users)

- Severe diarrhea; there may be an inflammation of the intestines caused by a certain bacterium (*Clostridium difficile*), which can grow because other bacteria disappear due to the action of clindamycin. Therefore, inform your doctor if you get diarrhea (see also section 2 "When should you be extra careful with this medicine?"), diarrhea, abdominal pain, stomach pain, inflammation of the oral mucosa.
- Abnormal liver function test, increase in serum transaminases.

Sometimes (occur in less than 1 in 100 users)

- Deficiency of certain white blood cells leading to more frequent infections (granulocytopenia).
- Blockade of nerves and muscles (neuromuscular blocking effect).
- Vomiting, nausea.
- Rash characterized by a flat, red area on the skin covered with small confluent bumps (maculopapular rash), skin rash with intense itching and bumps (hives, urticaria).

Rare (occur in less than 1 in 1,000 users)

- Sudden swelling of the skin and mucous membranes (e.g., throat or tongue), resulting in breathing difficulties and/or itching and rash, often as an allergic reaction (angioedema), swelling of the joints.
- Drug fever.

Very rare (occur in less than 1 in 10,000 users)

- Liver inflammation (hepatitis) with temporary jaundice.
- Inflammation of multiple joints (polyarthritis).

Not known (cannot be determined from the available data)

- *Clostridium difficile* colitis, infection of the vagina (mucous membrane).
- Severe blood disorder with significantly fewer white blood cells causing sudden high fever, severe sore throat, and mouth ulcers (agranulocytosis), deficiency of white blood cells leading to increased susceptibility to infections (neutropenia, leukopenia), deficiency of platelets with symptoms of bruising and increased risk of bleeding (thrombocytopenia), increase in certain white blood cells (eosinophils).
- Severe allergic reaction, with a sharp drop in blood pressure, paleness, restlessness, weak rapid heartbeat, clammy skin, and reduced consciousness due to sudden widening of blood vessels (anaphylactic shock), hypersensitivity reactions requiring immediate medical intervention (anaphylactoid reaction, anaphylactic reaction), hypersensitivity.
- Taste disorder, smell disorder, headache, drowsiness, dizziness.

- Esophageal ulcer, inflammation of the esophagus.
- Jaundice.
- Severe, sudden allergic reaction, with symptoms of fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis; Lyell's syndrome), severe allergic reaction with high fever, blisters on the skin, joint pain and/or eye inflammation (Stevens-Johnson syndrome), severe allergic reaction with rash, fever, and swelling of the face and oral mucosa, transient increase in the amount of a certain type of blood cells (eosinophils) and possible jaundice, joint pain (arthralgia) and inflammation of the kidneys with symptoms of blood in urine, fever, and side pain (interstitial nephritis) (DRESS syndrome), acute skin rash characterized by a sudden outbreak of pus-filled blisters with a red surrounding skin (acute generalized exanthematous pustulosis (AGEP)), skin inflammation characterized by peeling of the skin (dermatitis exfoliativa), skin inflammation with blister formation (dermatitis bullosa), rash with irregular red spots (erythema multiforme), itching (pruritus), hypersensitivity (allergy) in the form of measles-like rash (morbilliform rash).

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb. Website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Store below 25°C.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. This can be found on the box or blister after "Exp.". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is clindamycin. The capsules contain clindamycin hydrochloride monohydrate, equivalent to 150 mg or 300 mg anhydrous clindamycin per capsule.
- The other substances in this medicine are: corn starch, lactose, talc, and magnesium stearate. The capsules consist of gelatin, iron oxide (E172), and titanium dioxide (E171).

What does Clindamycin Sandoz look like and what is in a package?

Clindamycin Sandoz capsules are available in two strengths. Clindamycin Sandoz 150 mg capsules are brown/reddish-brown in color and Clindamycin Sandoz 300 mg capsules are brown/brown in color.

Clindamycin Sandoz capsules are available in patient packs of 30 or 60 capsules in blister strips.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Netherlands

Manufacturers

Salutas Pharma GmbH Otto-von-Guericke Allee 1

39179 Barleben Germany

S.C. Sandoz S.R.L. Str. Livezeni nr.7^a Târgu Mureş

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Romania

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