

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[NT020 trade name][†]

Azithromycin

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [NT020 trade name] is and what it is used for
2. What you need to know before you take [NT020 trade name]
3. How to take [NT020 trade name]
4. Possible side effects
5. How to store [NT020 trade name]
6. Contents of the pack and other information

1. What [NT020 trade name] is and what it is used for

[NT020 trade name] contains azithromycin. Azithromycin is an antibiotic that belongs to a group of antibiotics known as macrolides, which block the growth of susceptible bacteria.

[NT020 trade name] is used to treat or prevent certain bacterial infections in adults, teenagers and children above 6 months of age, including some treatments that are given to a whole community to control a disease and stop it spreading. Your health care provider will explain what you are being given this medicine for

2. What you need to know before you take [NT020 trade name]

Do not take [NT020 trade name]

- if you are allergic to azithromycin, erythromycin, any macrolide or ketolide antibiotic, or any of the other ingredients of this medicine (listed in section 6).

Speak with your health care provider if you are not sure whether you can take [NT020 trade name].

Warnings and precautions

Talk to your health care provider before taking [NT020 trade name] if you have ever had any of the following conditions:

- heart problems, particularly if you have been told you have
 - a condition called QT prolongation or other problems with your heart's electrical activity or rhythm
 - heart failure (cardiac insufficiency)

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- low levels of potassium or magnesium in your blood.

These conditions may make serious side effects on your heart more likely.

- liver problems: your health care provider may need to monitor your liver function or stop the treatment severe diarrhoea after taking antibiotics
- myasthenia gravis, a disease that causes muscle weakness: the symptoms of this disease may worsen during treatment

[NT020 trade name] is also not suitable to take with certain other medicines. Tell your health care provider about any other medicines you are taking (see ***Other medicines and [NT020 trade name]***, below, for more advice).

Speak with your health care provider if you need more information.

If you get any of the following serious symptoms while taking, or shortly after taking, this medicine, do not take any remaining doses and **contact your health care provider right away**:

- you feel you are having an allergic reaction (e.g. difficulty in breathing, swelling of the face or throat, rash, blistering).
- you get extensive rashes with blistering or ulcers of soft tissue like mouth or genitals, especially if you also have fever or flu-like symptoms. These may be signs of serious skin reactions that have been reported with azithromycin.
- you feel you have an abnormal heartbeat or palpitations, get dizzy or faint when taking [NT020 trade name].
- you lose your appetite, or get nausea (feel sick), or feel tired all the time, or you have a rash *and you have any of the following*
 - belly pain, usually on the right side and near the chest
 - unexplained itching
 - yellowing of the white parts of your eyes, your nails or your skin
 - passing dark urine
 - passing stools that are very pale

These are signs of a problem with your liver, which can become serious.

- you develop severe diarrhoea during or after treatment. Do not take any medicine to treat your diarrhoea without first checking with your health care provider. If your diarrhoea continues or reappears within the first weeks after treatment, please also inform your health care provider.

Other infections

If you are receiving treatment with [NT020 trade name] your health care provider may need to carry out checks to ensure that other infections that do not respond to this medicine are not present, or do not develop.

Other medicines and [NT020 trade name]

Tell your health care provider if you are taking or have recently taken any other medicines.

Taking [NT020 trade name] at the same time as some other medicines may result in side effects, sometimes serious. Therefore, it is particularly important that you tell your health care provider if you are using any of the following medicines:

- Atorvastatin and other medicines from the statins group (to lower blood cholesterol and prevent heart disease, including heart attacks and strokes)
- Ciclosporin (to prevent rejection of organ transplants by the body)
- Colchicine (to treat gout and familial Mediterranean fever)
- Dabigatran (to prevent and treat blood clot formation (anticoagulant))
- Digoxin (to treat heart diseases)
- Ergot derivatives such as ergotamine (used to treat migraine)
- Warfarin or similar medicines used to thin the blood (anticoagulants)
- Medicines that may cause the heart muscle to take longer to contract and relax than usual (QT prolongation), such as the following:

- Amiodarone, dofetilide, procainamide or sotalol (to treat an irregular heartbeat, including a too fast or too slow heartbeat - cardiac arrhythmia)
- Citalopram (to treat depression)
- Hydroxychloroquine or chloroquine (to treat autoimmune diseases including rheumatoid arthritis, or to treat or prevent malaria)
- Levofloxacin or moxifloxacin (antibiotics, including for tuberculosis)
- Pimozide (to treat mental illness)

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant or you are planning to have a baby, speak to your health care provider before taking this medicine.

Pregnancy

This medicine has been used in pregnant women without affecting their baby. However, because information on such use is limited, if you are pregnant your health care provider will discuss the risks and benefits of treatment with you..

Breast-feeding

[NT020 trade name] passes into breast milk. Your health care provider will discuss with you whether you should temporarily stop breast-feeding or should avoid treatment with [NT020 trade name], taking into account both the benefit of breast-feeding for your child and the benefit of therapy for you.

Driving and using machines

[NT020 trade name] has been reported to cause dizziness, drowsiness and seizures, as well as problems with seeing and hearing in some people. Do not operate machines or drive if you feel dizzy after taking [NT020 trade name].

Important information about some of the ingredients

This medicine contains lactose monohydrate. Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

3. How to take [NT020 trade name]

Always take this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

The amount of [NT020 trade name] that you need to take each day depends on the bacterial infection that you are being treated for, and for some conditions on your age and weight as well.

[NT020 trade name] should be taken by mouth as a single daily dose. Tablets should be swallowed whole with some water. [NT020 trade name] can be taken with food or between meals. Taking this medicine just before a meal may help make it easier on your stomach.

If you take more [NT020 trade name] than you should

If you take more tablets than you should then you may feel unwell. Typical signs of an overdose are vomiting, diarrhoea, abdominal pain and nausea. Tell your health care provider or contact your nearest hospital emergency department immediately.

If you forget to take [NT020 trade name]

If you forget to take [NT020 trade name] at your usual time, and there is at least 12 hours to go before your next dose is due, then take the missed dose as soon as you can. If there are less than 12 hours left to your next dose, skip the missed dose and take the next dose at the proper time. Do not take a double dose to make up for a forgotten dose.

If you stop taking [NT020 trade name]

If you have been given a course of tablets to take and you stop taking [NT020 trade name] too soon, the infection may return. Take [NT020 trade name] for the full time of treatment, even when you begin to feel better.

If you have any questions on this medicine, ask your health care provider.

4. Possible side effects

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

Serious side effects

Stop using [NT020 trade name] and seek medical attention immediately if you notice any of the following symptoms:

- sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching especially affecting the whole body (*anaphylactic reaction*, frequency not known)
- rapid or irregular heartbeat (*cardiac arrhythmia or torsades de pointes tachycardia*, frequency not known)
- liver disorders, which can cause yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, fatigue, weakness, (*hepatic failure or hepatic necrosis* (frequency not known)).
- severe diarrhoea with abdominal cramps, bloody stools and/or fever may mean that you have an infection of the large intestine (*antibiotic-associated colitis*, frequency not known). Do not take medicines against diarrhoea that inhibit the bowel movements (*antiperistaltics*).
- reddish, target-like or circular patches on the torso, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (*Stevens-Johnson syndrome or toxic epidermal necrolysis*, frequency not known).
- widespread rash, high body temperature and enlarged lymph nodes (*DRESS syndrome or drug hypersensitivity syndrome*, rare (may affect up to 1 in 1,000 people)).
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (*acute generalised exanthematous pustulosis*, rare (may affect up to 1 in 1,000 people)).

Other side effects that may be seen with this medicine:

Very common side effects (more than 1 in 10 people can get this side effect)

- diarrhoea

Common side effects (up to 1 in 10 people can get this side effect)

- headache
- being sick (*vomiting*), stomach pain, feeling sick (*nausea*)
- changes in blood test results (*lymphocyte count decreased, eosinophil count increased, basophil count increased, monocyte count increased, neutrophil count increased, blood bicarbonate decreased*)

Uncommon side effects (up to 1 in 100 people can get this side effect)

- thrush (*candidiasis*) - a fungal infection of the mouth and vagina, other fungal infections
- pneumonia, bacterial infection of the throat, inflammation of the gastrointestinal tract, respiratory disorder, inflammation of the mucous membrane inside the nose, vaginal infection
- changes in the number of white blood cells (*leukopenia, neutropenia, eosinophilia*)
- platelet count increased
- reduction in the proportion of all blood cells in the total blood volume (*hematocrit decreased*)
- allergic reactions, swelling of the hands, feet and face (*angioedema*)
- lack of appetite
- nervousness, difficulty sleeping (*insomnia*)
- feeling dizzy, feeling drowsy (*somnolence*), change in your sense of taste (*dysgeusia*)[#], sensation of pins and needles or numbness (*paraesthesia*)
- impaired vision
- ear disorder

- spinning sensation (*vertigo*)
- feeling your heartbeat (*palpitations*)
- hot flush
- sudden wheeziness, bleeding from the nose
- constipation, wind, impaired digestion (*dyspepsia*), inflammation of the lining of the stomach (*gastritis*), difficulty in swallowing (*dysphagia*), swollen belly, dry mouth, belching (*eructation*), mouth ulceration, increased salivation
- rash, itching, hives (*urticaria*), dermatitis, dry skin, abnormally increased sweating (*hyperhidrosis*)
- swelling and pain in the joints (*osteoarthritis*), muscle pain, back pain, neck pain
- painful urination (*dysuria*), kidney pain
- menstrual bleeding at irregular intervals (*metrorrhagia*), testicular disorder
- swelling due to fluid retention, especially of the face, ankles and feet (*oedema*, *face oedema*, *peripheral oedema*)
- weakness, tiredness, general feeling of being unwell, fever
- chest pain, pain
- abnormal laboratory test results (e.g. blood or liver tests)

Rare side effects (up to 1 in 1,000 people can get this side effect)

- feeling agitated
- liver problems, yellowing of the skin or eyes
- increased sensitivity to sunlight

Other side effects (not known how often they can occur)

- reduced number of red blood cells due to increased cell breakdown which can cause tiredness and pale skin (*haemolytic anaemia*)
- reduction in number of blood platelets which can lead to bleeding and bruising (*thrombocytopenia*)
- feeling angry or aggressive, feeling anxious, sudden confusion and disorientation (*delirium*),
- hallucination
- fainting (*syncope*)
- fits (*seizures*)
- reduced sensation to touch, pain and temperature (*hypoesthesia*)
- feeling hyperactive
- change in your sense of smell (*anosmia*, *parosmia*)
- total loss of your sense of taste (*ageusia*)
- muscle weakness (*myasthenia gravis*)
- abnormalities in the electrical activity of the heart (*QT prolongation*)
- deafness, reduced hearing or ringing in your ears (*tinnitus*)
- low blood pressure
- inflammation of the pancreas causing severe pain in the belly and back (*pancreatitis*)
- black or brownish discoloured tongue
- joint pain (*arthralgia*)
- kidney inflammation (*interstitial nephritis*) and kidney failure

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [NT020 trade name]

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

Do not store above 30°C. Avoid excursions above 30°C. Protect from light and moisture.

Do not use this medicine after the expiry date stated on the label after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [NT020 trade name] contains

- The active ingredient is azithromycin dihydrate. Each film-coated tablet contains 500 mg of azithromycin (as dihydrate).
- The other ingredients of [NT020 trade name] are dicalcium phosphate, pregelatinized starch, croscarmellose sodium, hypromellose, sodium lauryl sulfate, magnesium stearate, lactose monohydrate, hypromellose, titanium dioxide, macrogol/PEG, talc and sodium lauryl sulphate.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [NT020 trade name] looks like and contents of the pack

White, round, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets are plain on both sides.

Clear colourless plastic (PVC or PVC/PVDC) on aluminium foil blister cards, each containing 3 tablets. Available in cartons of 10 x 3 tablets.

Supplier and Manufacturer

Supplier

Rusan Pharma Ltd.
58-D, Government Industrial Estate,
Charkop, Kandivali (West),
Mumbai - 400 067
Maharashtra
India
Tel.: + 91 022 28682512/15, 42383000
Fax: + 91 022 28689056
E-mail: Rusan@rusanpharma.com

Manufacturer

Rusan Pharma Ltd.
Khasra No. 122 MI, Central Hope Town,
Selaqui, District: Dehradun - 248197
Uttarakhand
India
Tel.: + 91 9193011244
E-mail: prashant.asthana@rusanpharma.com

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in March 2026

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>