SCHEDULING STATUS

S4

NIDASALL 200 (Tablets)

Contains sugar: Lactose 100 mg

NIDASALL 400 (Tablets)

Contains sugar: Lactose 80 mg

Metronidazole 200 mg and 400mg

Read all of this leaflet carefully before you start taking NIDASALL.

- Keep this leaflet. You may need to read it again
- Do not share **NIDASALL** with any other person
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. **What NIDASALL is and what is it used for:**

   NIDASALL contains metronidazole, and it works by killing bacteria and parasites that cause infections in your body.

   It can be used to:

- Treat infections caused by certain bacteria
- Prevent infections after surgery.

2. What you need to know before you take NIDASALL:

Do not take NIDASALL if :

- You are allergic (hypersensitive) to metronidazole or any of the other ingredients in **NIDASALL** (listed in section 6).
- You are taking a medicine called, busulfan (treatment for cancer of blood cells) (see warning and precautions)

Warnings and precautions

Take special care with NIDASALL if you have:

- blood dyscrasias (disease of the blood with low/lack of certain blood cells)
- active or chronic disease of the central (nerves of the brain and spinal cord) and peripheral (nerves outside the brain and spinal cord) nervous system.
- hepatic encephalopathy (worsening of brain function that occurs when the liver is no longer able to remove toxic substances in the blood).
- cancer of the blood cells for which you are receiving treatment with a medicine called Busulfan. Co-administration with busulfan may lead to severe busulfan toxicity and death.

Do not take alcohol beverages and medicine containing alcohol during therapy and for at least 1 to 3 days afterwards

Pseudomembranous colitis (infection of the colon) has been reported with the use of **NIDASALL**. Tell your doctor immediately if you develop watery and severe diarrhoea, which may also be bloody.

Your doctor will lower the dose of **NIDASALL** if you suffer with severe liver disease.

If you are taking **NIDASALL** for more than 10 days your doctor will monitor you and will discontinue treatment if signs of peripheral neuropathy (disorder of the nerves which can cause weakness, tingling or numbness) or central nervous system toxicity develop.

NIDASALL has anti-treponemal activity (bacteria that can cause syphilis) and may mask the immunological response (the body's natural defence) seen in untreated early syphilis. If you have syphilis and are receiving **NIDASALL** your doctor will continue testing you for syphilis for an additional 4 to 8 weeks.

NIDASALL may cause darkening of urine (due to the substance that **NIDASALL** is broken down into in the body).

Other medicines and NIDASALL:

Always tell your healthcare professional if you or your child are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Disulfiram for the treatment of alcoholism. Taking **NIDASALL** with disulfiram can result in acute confusion.
- Alcohol or medicine containing alcohol (see Taking **NIDASALL** with food and drink).
- Medicines used to thin the blood such as warfarin. **NIDASALL** intensifies the effect of warfarin and may result in uncontrolled bleeding.
- Lithium for mental illness. Blood levels of lithium may be increased by **NIDASALL**.
- Phenytoin or phenobarbital for epilepsy reduce the effectiveness of **NIDASALL**.

- 5-Fluorouracil for cancer. **NIDASALL** may intensify the of harmful effects of 5-fluorouracil.
- Busulfan for leukaemia (cancer of the blood cells) (see Take special care with **NIDASALL**).
- Ciclosporin to prevent the rejection of organs after transplant. **NIDASALL** may increase the blood levels of ciclosporin.
- Cimetidine for stomach ulcers may intensify the effects of **NIDASALL**.

NIDASALL with food, drink, and alcohol:

Do not drink any alcohol or medicine containing alcohol while you are taking **NIDASALL** and for 1 to 3 days after finishing your course. Drinking alcohol whilst you are being treated with **NIDASALL** might cause unpleasant side effects, such as:

- feeling sick (nausea),
- being sick (vomiting),
- stomach pain,
- hot flushes,
- very fast or
- uneven heartbeat (palpitations) and headache.

Pregnancy and breastfeeding and fertility:

The safety in pregnancy and lactation has not been established.

Tell your doctor before taking **NIDASALL** if:

- You are pregnant, might become pregnant or think you may be pregnant.
- You are breastfeeding. **NIDASALL** pass into the mother's milk and women taking **NIDASALL** should not breastfeed their infants.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **NIDASALL**.

Driving and using machines:

While taking **NIDASALL**, you may feel sleepy, dizzy, confused, see or hear things that are not there (hallucinations), have fits (convulsions) or temporary eyesight problems (such as blurred or double vision). (See POSSIBLE SIDE EFFECTS). If this happens, do not drive or use any machinery or tools.

It is not always possible to predict to what extent **NIDASALL** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NIDASALL affects them.

NIDASALL contains lactose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take NIDASALL:

Do not share medicines prescribed for you with any other person.

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

It is important to finish a full course of treatment. The length of a course will depend on your needs and the illness being treated.

If you have the impression that the effect of **NIDASALL** is too strong or too weak, tell your doctor or pharmacist.

Taking this medicine

Swallow the tablets whole with a little water.

Do not crush or chew the tablets.

Take these tablets during or just after a meal.

The dose of **NIDASALL** will depend on your needs and the illness being treated.

The length of your treatment will depend on the type of illness you have and how bad it is.

The usual dose is:

To treat bacterial infection

Adults

- The initial dose is 800mg.
- After 8 hours take another dose of 400mg and repeat this dose every 8 hours.

Children

- Your doctor will work out how much your child should take depending on their weight.
- Repeat the dose every 8 hours.

To prevent infections from happening after surgery

Adults

- Start taking **NIDASALL** Tablets 24 hours before your operation.
- Take 400 mg of **NIDASALL** every 8 hours.
- After the operation you may be given **NIDASALL** either through a drip into a vein or rectally as a suppository until you are able to take tablets again.

Children

- Give your child **NIDASALL** Tablets 1-2 hours before their operation.

- Your doctor will work out how much your child should take depending on their weight.
- After the operation your child may be given **NIDASALL** either through a drip into a vein or rectally as a suppository until they are able to take tablets again.

Other types of infections

For treatment of other infections caused by parasites and some bacteria your doctor will decide how much **NIDASALL** you need to take and how often. This will depend on your illness and how bad it is.

If you take more NIDASALL than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of NIDASALL:

Try to take **NIDASALL** as prescribed by your healthcare professional. However, if you miss a dose, do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

NIDASALL can have side effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking NIDASALL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching)
- Urticaria (pinkish, itchy, lumpy rash called hives or nettle rash)

- Angioedema (swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing)

Tell your doctor if you notice any of the following

Frequent side effects:

- Gastrointestinal disturbances, especially nausea (feeling sick) and taste disorders; nausea is sometimes accompanied by headache, and vomiting (being sick). Diarrhoea, dry mouth, a furred tongue, oral mucositis (sore/red mouth) and stomatitis (sore mouth, mouth ulcers and cold sores)

Less frequent side effects:

- Agranulocytosis, neutropenia and thrombocytopenia (blood problems with unexpected infections, mouth ulcers, bleeding or bruising more easily than normal)
- Psychotic disorders including confusion, irritability and hallucinations (seeing or hearing things that are not there), changes in mood or mental state such as depression or confusion
- Weakness, dizziness, drowsiness, insomnia (sleep disorder). Reports of encephalopathy (brain disease, symptoms of which vary but you may get a fever, stiff neck, headache and see or hear things that are not there) and subacute cerebellar syndrome (where you encounter problems with coordination of movement of your arms and legs, problems speaking or feel confused)
- Vision disorders such as diplopia (double vision) and myopia (short sightedness)
- Pseudomembranous colitis (watery and severe diarrhoea, which may also be bloody)
- Increase in liver enzymes (liver problem) and inflammation of the liver sometimes with jaundice (liver disease with nausea, vomiting, loss of appetite, feeling

generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine)

- Pustular eruptions (breakouts of blisters, containing pus, on the skin), mild erythematous eruptions (mild redness) with fleeting (brief) joint pains resembling serum sickness (allergic reaction to an injection of serum)
- Urethral (bladder) discomfort and darkening of the urine

Frequency unknown

- Leucopenia (lack of white blood cells)
- Angioedema (swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing), urticaria (pinkish, itchy, lumpy rash called hives or nettle rash)
- Anorexia (loss of appetite)
- Peripheral neuropathy (a disorder of the nerves), usually presenting as numbness, tingling, or a feeling of weakness in the arms or legs and, fits (convulsions) are serious adverse effects on the nervous system that have been associated especially with high doses of **NIDASALL** of prolonged treatment
- Nasal congestion (blocked/stuffy nose)
- Pancreatitis (inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting) and raised liver enzyme values (liver problem)
- Skin rashes, fever, flushing (reddening of skin), and pruritus (itching)
- Myalgia (pains in the muscles) and arthralgia (pains in the joints)
- Fever

- Headache, aseptic meningitis (inflammation of the membranes around the brain and spinal cord with fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light)
- Eyesight problems such as blurred vision, decreased in visual acuity (sharpness of vision), changes in colour vision
- Optic neuritis (pain in your eyes and increasingly blurred vision)
- Epigastric pain (pain in the upper central region of the stomach)
- Mixed hepatitis and hepatocellular liver injury (liver diseases)
- Cases of liver failure requiring liver transplant have been reported in patients treated with **NIDASALL** in combination with other antibiotic medication

If you notice any side effects not mentioned in this leaflet, please inform your doctor

Reporting of side effects

If you get side effects, talk to your doctor or , pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **NIDASALL.**

Innovata Pharmaceuticals Contact Details: regulatory@innovata.co.za

HOTLINE for reporting of side effects directly to Innovata Pharmaceuticals (Pty) Ltd: 086 999 0912

5. How to store NIDASALL

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

Store **NIDASALL** at or below 25 °C in original container. Protect from light and moisture. Do not use this medicine after the expiry date shown on the pack.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

6. Contents of the pack and other information

What NIDASALL contains:

The active substance is: Metronidazole

The other ingredients are: Lactose, maize starch, magnesium stearate, pregelatinised maize starch, purified talc, quinoline yellow.

What NIDASALL looks like and contents of the pack

NIDASALL 200: White, biconvexed, scored tablet.

NIDASALL 400: Yellow, biconvexed, scored tablet.

Nidasall 400: Securitainer containing 100 or 500 tablets.

"Ziploc' patient ready L.D.P.E. plastic bags of different pack sizes (5, 14 or 21 tablets).

Nidasall 200: Securitainer containing 250 tablets.

"Ziploc' patient ready L.D.P.E. plastic bags of different pack sizes (21 or 28 tablets).

Holder of Certificate of Registration

Innovata Pharmaceuticals Pty Ltd

Crownwood Office Park

100 Northern Parkway

Building D

Ormonde

Johannesburg

2091

This leaflet was revised in

Date of first authorization October 2020

Date of revision 22/10/2025

Registration number

400 mg Tablets: 28/20.2.6/0037

200 mg Tablets: 28/20.2.6/0036

Access to the corresponding Professional information.

Is contained in the packaging or follow the link for the corresponding Professional

Information for Nidasall:

pi-pil-repository.innovata.co.za,

alternatively, please scan the QR code below