SPORANOX® CAPSULES

Itraconazole (100mg)

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What SPORANOX® is used for

SPORANOX capsules are used to treat certain fungal infections which include the following:

- persistent infections of the nails, skin, hands, feet or groin;
- persistent candida (yeast) infections of the vagina;
- eye infections which have not responded to other treatment or which may be affecting vision;
- candida (yeast) infections of the mouth or throat in patients with lower resistance to disease;
- generalised infections.

Your doctor may have prescribed SPORANOX capsules for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

How SPORANOX® works

SPORANOX works by killing or stopping the growth of the fungus that causes the infection.

Before you use SPORANOX®

- *When you must not use it*

  Do not use SPORANOX:
  - if you know you are hypersensitive (allergic) to it;
  - if you are pregnant (unless your doctor knows you are pregnant and decides you need SPORANOX);
  - if you are of child bearing age and could become pregnant, you should take adequate contraceptive precautions to make sure that you do not become pregnant while you are taking your medicine. As SPORANOX remains in the body for some time after you stop taking it, you should continue to use contraception until your next period after your treatment with SPORANOX capsules is finished. If you are breast-feeding, tell your doctor before taking SPORANOX.
  - if you have a condition called heart failure (also called congestive heart failure or CHF), SPORANOX could make it worse. If your doctor decides that you need to take SPORANOX even if you have this condition, be sure to get immediate medical help if you have shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night.

  Also, do not use certain medicines if you are on SPORANOX capsules. There are many medications that interact with SPORANOX capsules. Please refer to the section "Before you use SPORANOX®", subsection "Taking other medicines".

- *Before you start to use it*
  - Always tell your doctor or pharmacist if you are taking any other medicine.
  - Tell your doctor if you know you have a liver and/or kidney disorder. The dose of SPORANOX capsules may need to be adjusted.
  - Stop taking SPORANOX capsules and see your doctor immediately should any of the following symptoms appear during the SPORANOX treatment: lack of appetite, nausea, vomiting, tiredness, abdominal pain, yellow color to skin or eyes, pale stools or very dark urine.
  - Tell your doctor if you have a heart problem and if you develop shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night.
  - Tell your doctor or get medical assistance immediately if you experience a significant skin rash, itching, hives, difficulty breathing, and/or swollen face while taking SPORANOX capsules.
  - capsules and tell your doctor immediately if you become oversensitive to sunlight or experience a widespread rash with peeling skin and blisters in the mouth, eyes and genitals, or a rash with small pustules or blisters.
  - Stop taking SPORANOX capsules and tell your doctor immediately if you develop any feelings of tingling, diminished sensation or weakness in your limbs, or other problems with the nerves in the arms or legs.
  - Tell your doctor if you had experienced an allergic reaction to SPORANOX or another antifungal.
  - Tell your doctor if you have cystic fibrosis before using SPORANOX capsules.
  - Tell your doctor if you are a neutropenic, AIDS, or organ transplant patient.
  - Stop taking SPORANOX capsules and tell your doctor immediately if you experience any hearing loss symptoms.
  - Tell your doctor if your vision gets blurry or you see double, if you hear a ringing in your ears, if you lose the ability to control your urine or urinate much more than usual.

- *Taking other medicines*

  Tell your doctor or pharmacist what medicines you are currently taking. This is not a complete list of medicines. Therefore, tell your doctor about all medicines you take.

  Medicines that must never be taken while you are on SPORANOX capsules:

- medicines used for allergy such as terfenadine;
- medicines used in heart-related conditions such as felodipine (for angina; crushing chest pain, or high blood pressure), ticagrelor (for blood clotting), simvastatin (for high cholesterol), and dronedarone (for irregular heart beat rhythms);
- gastrointestinal medications such as cisapride (to treat certain digestive problems), domperidone (for nausea and vomiting) and naloxegol (for constipation due to opioid intake)
- medicines used for central nervous system such as midazolam (as sleeping pills), lurasidone (for psychotic disorders), methadone (for severe pain or to manage addiction) and ergotamine (for migraine headaches),
- anti-infective medicines such as halofantrine (for malaria), and isavuconazole (for fungal infections).
- anti-cancer medicines such as irinotecan, mobocertinib;
- medicines used to control bleeding and maintain uterine contraction after child birth such as ergometrine (ergonovine) or methylergometrine (methylergonovine) ;
- medicine used to treat erectile dysfunction such as avanafil;
- medicine used to treat premature ejaculation; dapoxetine;
- medicines used to treat kidney problems in patients with type 2 diabetes; finerenone;
- medicines to treat lupus-related kidney problems; voclosporin.

Medicines that must never be taken while you are on SPORANOX capsules, if you have kidney or liver impairment

- medicine used to treat gout; colchicine;
- telithromycin (for bacterial infections)
- medicines when used to control irritated urinary bladder; fesoteridine or solifenacin;

Medicines that must never be taken while you are on SPORANOX capsules, if you know you do not break down drugs that are handled/broken down by the enzyme CYP2D6:

- eliglustat

Medicines that must never be taken while you are on SPORANOX capsules during or for at least 2 weeks after the final dose:

- mavacamten

Medicines that must never be taken while you are on SPORANOX capsules, if you have chronic lymphocytic leukemia/small lymphocytic lymphoma and you want to newly start this medicine or are making dose adjustments:

- venetoclax

Medicines that are not recommended, because they can decrease the action of SPORANOX capsules:

- anti-epileptic medicine such as carbamazepine and phenytoin;
- anti-infective drugs, such as rifampicin (for tuberculosis) and efavirenz (for HIV/AIDS);

Medicines that are not recommended unless your doctor feels it is necessary:

- anti-cancer medicines such as docetaxel, entrectinib, glasdegib, ibrutinib, talazoparib and trabectedin;
- medicines used in heart-related conditions such as sildenafil (for pulmonary hypertension; increased blood pressure in the blood vessels in the lungs), conivaptan (for low blood sodium), apixaban, edoxaban (to slow down blood clotting), aliskiren (for high blood pressure) and vorapaxar (for heart attacks or stroke);
- medicines usually given after an organ transplant; everolimus, rapamycin (also known as sirolimus);
- anti-infective drugs, such as bedaquiline (for tuberculosis)
- medicines related to male health, such as alfuzosin (for Benign Prostatic enlargement), tamsulosin (for male urinary incontinence) and vardenafil (erectile dysfunction),
- medicine used to treat gout; colchicine;
- medicine used to treat urinary incontinence; darifenacin,
- medicine used to treat pain; fentanyl (a strong medicine to treat pain);
- medicine used to improve breathing; salmeterol;
- medicine used to treat diarrhea; Saccharolmyces boulardii;
- medicine used to treat Cystic Fibrosis; lumacaftor/ivacaftor.
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- *Medicines not recommended while you are on SPORANOX capsules, when you are on a stable dose of this medicine for chronic lymphocytic leukemia/small lymphocytic lymphoma, or at any time of treatment for acute myeloid leukemia:*venetoclax

Medicines that may require a dose change:

- anti-infective medications such as ciprofloxacin (antiobiotics), delamanid (for tuberculosis), trimetrexate (for pneumonia in patients with immune system problems), ritonavir (for HIV/AIDS), boceprevir (for Hepatitis C Virus), praziquantel (for fluke and tapeworms) and telithromycin (for pneumonia).
- medicines for heart-related conditions such as digoxin (for heart failure), diltiazem (for high blood pressure), warfarins (for slowing down the blood clotting), atorvastatin (for high cholesterol) and mozavaptan (for low blood sodium)
- medicines related with central nervous system such as guanfacine (for Attention Deficit Hyperactivity Disorder), buspirone (for anxiety or as sleeping pills),aripiprazole (for psychosis), suvorexant (for

insomnia), venlafaxine (for depression and anxiety), cabergoline (for Parkinson's disease) and eletriptan (for migraine headache);
- anti-inflammatory medicines such as methylprednisolone;
- medicines which are usually given after an organ transplant; cyclosporine, tacrolimus;
- contreptive medicines; dienogest, ulipristal;
- anti-cancer medicines such as bortezomib, pemigatinib, tretinoin (oral),
- strong painkillers such as alfentanil, oxycodone;
- medicines used to treat diabetes; repaglinide, saxagliptin;
- gastrointestinal medicines such as aprepitant (for nausea and vomiting during cancer treatment), loperamide (for diarrhea) and cannabinoids (for nausea and vomiting in patients with multiple sclerosis)
- medicines used to control irritated urinary bladder such as fesoterodine;
- medicines related with male health, such as dutasteride (for benign prostatic enlargement) and sildenafil (for erectile dysfunction)
- medicines used for allergy such as bilastine;
- medicines used to treat joint inflammation and pain; meloxicam;
- medicines used to treat an overactive parathyroid; cinacalcet;
- medicine used to treat eczema; alitretinoin (oral formulation);
- medicine used to treat pneumonia; telithromycin;
- medicine used to treat Cystic Fibrosis; ivacaftor;
- medicines to treat Alzheimer's disease; galantamine
- medicines to treat Hepatitis C; glecaprevir/pibrentasvir; elbasvir/grazoprevir; ombitasvir/paritaprevir/ritonavir (with or without dasabuvir) combinations
- medicine to treat movements of the mouth, tongue, jaw and sometimes limbs, which cannot be controlled (tardive dyskinesia); valbenazine

Wait at least 2 weeks after stopping SPORANOX capsules before starting these medicines unless your doctor feels it is necessary.

How to use SPORANOX®
You should always take SPORANOX capsules immediately after a complete meal. Swallow the capsules whole with some water. How much and how long you will need to take SPORANOX will depend on your doctor's recommendations.

- <u>*How much to use*</u>
  Always stick to the instructions from your doctor, who may adapt the treatment to your personal needs.

  Vaginal infection
  2 capsules twice daily for 1 day
  or
  2 capsules once daily for 3 days

  Skin infection
  Depending on the extent of the infection, your doctor will choose the dosage and treatment period.
  1 or 2 capsules once daily or twice daily for between 5 and 15 days
  If the palms of your hands or soles of the feet are involved, you may need to take SPORANOX capsules for 30 days.

  With skin infections, the lesions will completely disappear a few weeks after the end of treatment with SPORANOX capsules. This condition is normal in fungal infection.

  Mouth infection
  1 capsule once daily for 15 days

  Eye infection
  2 capsules once daily for 21 days

  Internal infection
  1 to 4 capsules daily for longer periods

  Higher doses with SPORANOX capsules maybe be required for a longer duration.

  Nail infection
  Depending on your personal needs, your doctor will choose either continuous or cyclic therapy.
  - Continuous therapy for toenail infection: 2 capsules once daily for 3 months
    Cyclic nail therapy: 2 capsules twice daily for 1 week.
    After that stop taking SPORANOX for 3 weeks. Then the cycle is repeated, once for fingernail infections and twice for toenail infections (with or without fingernail infections)

  Nail lesions disappear 6 to 9 months after the end of treatment with SPORANOX capsules. That nail still needs to grow back after the fungus is killed in the infected nail; nail regrowth takes many months. So, do not worry if you notice no improvement during your treatment: the medicine will remain in your nail for several months to kill the fungus. You should therefore stop treatment as instructed by your doctor, even though you do not see any improvement.

- <u>*When to use it*</u>
  Always take SPORANOX exactly as your doctor has told you. You should check with your doctor if you are not sure.

- <u>*How long to use it*</u>
  Continue taking SPORANOX for as long as your doctor recommends.

- <u>*If you forget to use it*</u>
  - Take the dose you missed as soon as you remember, and then continue to take it as you would normally.
  - If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.
  - Do not take a double dose to make up for the one you missed.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

- *If you use too much (overdose)*
  Tell your doctor immediately if you have taken too much SPORANOX. They will take the necessary measures.

While you are using it

- *Things you must do*
  - Always follow your doctor's instructions carefully.
  - If you must take SPORANOX capsules continuously for more than 1 month, your doctor may ask you to have your blood checked regularly.
  - If there is any chance of you becoming pregnant, talk to your doctor about the need for an adequate contraception. Once you have finished taking SPORANOX, you should continue using adequate contraception until you have had your next period. Tell your doctor immediately if you do become pregnant while taking SPORANOX.
  - If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking SPORANOX capsules.
  - Always complete the treatment as directed by your doctor, even if the signs of infection have gone.

- *Things you must not do*
  - Do not take SPORANOX capsules to treat any other complaint unless your doctor says so.
  - Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

- *Things to be careful of*
  Driving and using machines
  SPORANOX can sometimes cause dizziness, blurred/double vision or hearing loss. If you have these symptoms, do not drive or use machines.

Side effects

Like all medicines, SPORANOX can cause side effects, although not everybody gets them. Tell your doctor if you notice any of the following side effects while using SPORANOX:

- The following symptoms may occur: upset stomach, nausea, vomiting, diarrhea, abdominal pain, constipation, or excess gas in stomach. Shortness of breath, cough, fluid in the lungs, altered voice, inflammation of the sinuses, inflammation of the nose, upper respiratory tract infection, headache, menstrual disorder, erectile dysfunction, dizziness, confusion, tremor, sleepiness, fatigue (lethargy), chills, tingling, numbness, muscle weakness or pain, painful joints, pain, chest pain, swelling, generalized swelling, inflammation of the pancreas, unpleasant taste, fever, excessive sweating, or hair loss may also occur. In addition, increase in heart rate, decrease in heart rate, increase in blood pressure, decrease in blood pressure, or heart failure may also occur.
- Hypersensitivity to SPORANOX capsules can occur. It can be recognized by skin rash, itching, hives, shortness of breath or difficulty breathing, and/or swollen face.
- You may experience one or more of the following symptoms that may be related to heart failure: shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night.
- One or more of the following symptoms that may be related to liver disorders may appear: lack of appetite, nausea, vomiting, tiredness, abdominal pain, jaundice, very dark urine, and pale stools.
- Your vision could get blurry or you could see double. You could hear a ringing in your ears. You could lose the ability to control your urine or urinate much more than usual. You may experience temporary or permanent hearing loss.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Storage and disposal of SPORANOX®

- *Storage*
  Keep out of reach and sight of children.

  This medicine can be kept for only a limited period. Do not use SPORANOX after the date (month and year) printed after "EXP", even if it has been stored properly.

  Return old medicines to your pharmacist.

- *Disposal*

If your doctor tells you to stop taking SPORANOX capsules or your medicines has passed its expiry date, ask your pharmacist what to do with any medicine which may be left over.

Product description

- *What it looks like*
  SPORANOX capsules comes in pink-blue capsules.

- *Ingredients*
  - Active ingredient
    The active ingredient in SPORANOX capsules is itraconazole.
    1 capsule contains 100 miligrams itraconazole.

  - Inactive ingredients
    The capsules also contain hypromellose, macrogol, and sugar spheres (composed of maize starch, purified water, and sucrose); the capsule itself is composed of erythrosine sodium, gelatin, indigotin disulfonate sodium, and titanium dioxide.

- *MAL number*
  MAL05072016AZ

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Date of revision
21/07/2026 (MY PI based on CCDS v04Dec2025)

Serial Number
NPRA (R1/7) 05112024/200