

## ข้อมูลยาภาษาอังกฤษสำหรับผู้ป่วย

### **SPORAL® (itraconazole (INN: Itraconazole)) CAPSULES**

#### **SPORAL®**

#### *Capsules*



#### **WHAT IS SPORAL CAPSULES FOR?**

SPORAL is a medicine used to treat fungal infections of the vagina, skin, mouth, eyes, nails or internal organs.



#### **WHEN NOT TO TAKE SPORAL CAPSULES**

Do not use SPORAL:

- if you know you are hypersensitive (allergic) to it;
- if you are pregnant (unless your doctor knows you are pregnant and decides you need SPORAL);
- 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 SPORAL 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 SPORAL capsules is finished.
- if you have a condition called heart failure (also called congestive heart failure or CHF), SPORAL could make it worse. If your doctor decides that you need to take SPORAL 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 SPORAL capsules. There are many medications that interact with SPORAL capsules. Please refer to the section "What Special Precautions Should You Take?", subsection "Other medicines".

#### **WHAT SPECIAL PRECAUTIONS SHOULD YOU TAKE?**

- Always tell your doctor or pharmacist if you are taking any other medicine because taking some medicines together can be harmful.
- Tell your doctor if you know you have a liver problem. The dose of SPORAL capsules may need to be adjusted.
- Stop taking SPORAL capsules and see your doctor immediately should any of the following symptoms appear during the SPORAL treatment: lack of appetite, nausea, vomiting, tiredness, abdominal pain, yellow color to skin or eyes, pale stools (bowel

movements) or very dark urine. If you have to take SPORAL capsules your doctor may also ask you to have your blood checked regularly. The reason for this is to rule out liver disorders in timely fashion, since such disorders can occur very rarely.

- Tell your doctor if you have a heart problem. Tell your doctor immediately if you develop shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue, or begin to wake up at night as these may be symptoms of heart failure.
- Tell your doctor if you have a kidney disorder. The dose of SPORAL capsules may need to be adjusted.
- Tell your doctor or get medical assistance immediately if you have a severe allergic reaction (characterized by significant skin rash, itching, hives, difficulty breathing, and/or swollen face) while taking SPORAL capsules.
- Stop taking SPORAL capsules and tell your doctor immediately if you become oversensitive to sunlight.
- Stop taking SPORAL capsules and tell your doctor immediately if you experience a severe skin disorder such as a widespread rash with peeling skin and blisters in the mouth, eyes and genitals, or a rash with small pustules or blisters.
- Stop taking SPORAL 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 SPORAL or another antifungal.
- Tell your doctor if you have cystic fibrosis before using SPORAL capsules.
- Tell your doctor if you are a neutropenic, AIDS, or organ transplant patient. The dose of SPORAL capsules may have to be adapted.
- Stop taking SPORAL capsules and tell your doctor immediately if you experience any hearing loss symptoms. In very rare cases, patients taking SPORAL have reported temporary or permanent hearing loss.
- 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.
- If you have hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency, you should not take this medicine.



## **Pregnancy**

Do not use SPORAL if you are pregnant.

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 SPORAL remains in the body for some time after you stop taking it, you should continue to use some form of contraception until your next period after your treatment with SPORAL is finished.



## Breast-feeding

If you are breast-feeding, tell your doctor before taking SPORAL; very small amounts of SPORAL could be present in your milk.



## Other medicines

Tell your doctor or pharmacist what medicines you are currently taking. In particular, some medicines must not be taken at the same time, and if certain medicines are taken at the same time, changes need to be made (to the dose, for example).

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

- terfenadine, astemizole, mizolastine; for allergy;
- bepridil, felodipine, nisoldipine, lercanidipine, ivabradine, ranolazine, eplerenone; to treat angina (crushing chest pain) or high blood pressure;
- ticagrelor; to slow down blood clotting;
- cisapride; to treat certain digestive problems;
- simvastatin, lomitapide, lovastatin; which lower the cholesterol;
- midazolam (oral), triazolam; sleeping pills;
- lurasidone, pimozide, sertindole; used for psychotic disorders;
- levacetylmethadol (levomethadyl), methadone; for severe pain or to manage addiction;
- halofantrine; to treat malaria;
- irinotecan, mobocertinib; anti-cancer drugs;
- dihydroergotamine or ergotamine (called ergot alkaloids); used in the treatment of migraine headaches;
- ergometrine (ergonovine) or methylergometrine (methylergonovine) (called ergot alkaloids); used to control bleeding and maintain uterine contraction after child birth;
- disopyramide, dronedarone, quinidine, dofetilide; to treat irregular heart beat rhythms;
- domperidone; to treat nausea and vomiting;
- isavuconazole; to treat fungal infections;
- naloxegol; to treat constipation caused by taking opioid painkillers;
- avanafil; to treat erectile dysfunction;

- dapoxetine; to treat premature ejaculation.
- finerenone; to treat kidney problems in patients with type 2 diabetes;
- voclosporin; to treat lupus-related kidney problems.

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

- colchicine, to treat gout;
- fesoteridine or solifenacin; when used to control irritated urinary bladder;
- telithromycin; an antibiotic.

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

- venetoclax

Wait at least 2 weeks after stopping SPORAL capsules before taking any of these medicines.

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

- carbamazepine, phenytoin, phenobarbital; to treat epilepsy;
- rifampicin, rifabutin, isoniazid; to treat tuberculosis;
- efavirenz, nevirapine; to treat HIV/AIDS.

You should therefore always tell your doctor if you are using any of these products so that the appropriate measures can be taken.

Wait at least 2 weeks after stopping these medicines before taking SPORAL capsules.

*Medicines not recommended unless your doctor feels it is necessary:*

- axitinib, bosutinib, carbazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, entrectinib, glasdegib, ibrutinib, lapatanib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, talazoparib, trabectedin, trastuzumab emtansine, vinca alkaloids; used in the treatment of cancer;
- riociguat, sildenafil, tadalafil; when used to treat pulmonary hypertension (increased blood pressure in the blood vessels in the lungs);
- everolimus, rapamycin (also known as sirolimus); usually given after an organ transplant;
- bedaquiline; rifabutin; to treat tuberculosis;
- conivaptan, tolvaptan; to treat low blood sodium;
- apixaban, edoxaban, rivaroxaban; to slow down blood clotting;
- alfuzosin, sildosin; to treat Benign Prostatic enlargement;

- aliskiren, to treat hypertension;
- sildenafil, when used to treat pulmonary hypertension (increased blood pressure in the blood vessels in the lungs);
- carbamazepine; to treat epilepsy;
- colchicine; to treat gout;
- darifenacin, to treat urinary incontinence;
- fentanyl; a strong medicine to treat pain;
- vorapaxar; to treat heart attacks or strokes;
- salmeterol; to improve breathing;
- tamsulosin; to treat male urinary incontinence;
- vardenafil; to treat erectile dysfunction.
- *Saccharomyces boulardii*; used to treat diarrhea;
- lumacaftor/ivacaftor; used to treat Cystic Fibrosis.

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

*Medicines not recommended while you are on SPORAL 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

Wait at least 2 weeks after stopping SPORAL capsules before starting this medicine unless your doctor feels it is necessary.

*Medicines that may require a dose change (for either SPORAL capsules or the other medicine):*

- ciprofloxacin, clarithromycin, erythromycin, telithromycin; antibiotics;
- delamanid, used to treat tuberculosis;
- trimetrexate; used to treat pneumonia in patients with immune system problems;
- bosentan, digoxin, nadolol, and certain calcium-channel blockers including verapamil; that act on the heart or blood vessels;
- guanfacine; used to treat Attention Deficit Hyperactivity Disorder;
- diltiazem; used to treat hypertension;
- coumarins (e.g. warfarin), cilostazol, dabigatran; that slow down blood clotting;
- methylprednisolone, budesonide, ciclesonide, fluticasone or dexamethasone (medicines given by mouth, injection or inhalation for conditions such as inflammations, asthma, and allergies);
- cyclosporine, tacrolimus, temsirolimus; which are usually given after an organ transplant;

- cobicistat, boosted elvitegravir, tenofovir disoproxil fumerate (TDF), maraviroc, and protease inhibitors: indinavir, ritonavir, boosted darunavir, ritonavir-boosted fosamprenavir, saquinavir; used in the treatment of HIV/AIDS;
- dienogest, ulipristal; used as contraceptives;
- boosted asunaprevir, boceprevir, daclatasvir, vaniprevir; used in the treatment of Hepatitis C Virus;
- bortezomib, brentuximab vedotin, busulphan, erlotinib, gefitinib, idelalisib, imatinib, ixabepilone, nintedanib, panobinostat, pemigatinib, ponatinib, ruxolitinib, sonidegib, tretinoin (oral), vandetanib; used in the treatment of cancer;
- buspirone, perospirone, ramelteon, midazolam IV, alprazolam, brotizolam; for anxiety or to help you sleep (tranquillizer);
- alfentanil, buprenorphine, oxycodone, sufentanil; certain strong medicines to treat pain;
- repaglinide, saxagliptin; to treat diabetes;
- aripiprazole, cariprazine, haloperidol, quetiapine, risperidone; to treat psychosis;
- suvorexant, zopiclone; to treat insomnia;
- aprepitant, netupitant; certain medicines to treat nausea and vomiting during cancer treatment;
- loperamide; to treat diarrhea;
- fesoterodine, imidafenacin, oxybutynin, solifenacin, tolterodine; to control irritated urinary bladder;
- dutasteride; used to treat Benign Prostatic enlargement;
- sildenafil, tadalafil, udenafil; to treat erectile dysfunction;
- praziquantel; to treat fluke and tapeworms;
- bilastine, ebastine, rupatadine; for allergy;
- reboxetine, venlafaxine; to treat depression and anxiety;
- atorvastatin; to lower cholesterol;
- meloxicam; to treat joint inflammation and pain;
- cinacalcet; to treat an over active parathyroid;
- mozavaptan; to treat low blood sodium;
- alitretinoin (oral formulation); to treat eczema;
- cabergoline; to treat Parkinsons Disease;
- cannabinoids; to treat nausea and vomiting, weight loss for patients with immune system problems and muscle spasms in patients with Multiple Sclerosis;
- valbenazine; to treat movements of the mouth, tongue, jaw, and sometimes limbs, which cannot be controlled (tardive dyskinesia);

- eletriptan; to treat migraine headaches;
- telithromycin; to treat pneumonia.
- ivacaftor; to treat Cystic Fibrosis.
- galantamine; to treat Alzheimer’s disease.
- glecaprevir/pibrentasvir; elbasvir/grazoprevir; ombitasvir/paritaprevir/ritonavir (with or without dasabuvir) combinations, to treat Hepatitis C.

*If you know you break down drugs that are handled/broken down by the enzyme CYP2D6 very quickly, you should check with your doctor if you can take this medicine as it may require a dose change:*

- eliglustat

Tell your doctor if you are using any of these medicines. This is **not** a complete list of medicines. Therefore, tell your doctor about **all** medicines you take.

There must be sufficient stomach acid to ensure that SPORAL capsules are properly absorbed by the body. Therefore, medicines that neutralize stomach acid should be taken at least 2 hours before SPORAL capsules or should not be taken sooner than 2 hours after SPORAL capsules. For the same reason, if you take medicines that stop the production of stomach acid, you should take your SPORAL capsules with a non-diet cola beverage.

If in doubt, consult your doctor or pharmacist.



### **Driving or operating machinery**

SPORAL can sometimes cause dizziness, blurred/double vision or hearing loss. If you have these symptoms, do not drive or use machines.



### **HOW TO TAKE SPORAL CAPSULES AND HOW MUCH**

You should always take SPORAL capsules immediately after a complete meal, because it works better this way. Swallow the capsules whole with some water. How much and how long you will need to take SPORAL will depend on the type of fungus infection and the place of infection in your body. Your doctor will tell you exactly what to do.

The following doses are used most frequently:

TYPE OF INFECTION	CAPSULES PER DAY	TIME PERIOD
* <b>Vaginal infection</b>	2 capsules twice daily or 2 capsules once daily	1 day or 3 days
* <b>Skin infection:</b> depending on your personal needs, your doctor will choose the dosage and treatment period.		
	1 or 2 capsules once daily or twice daily	Between 5 and 15 days
If the palms of the hands or soles of the feet are involved, you may need to take SPORAL capsules for 30 days.		
* <b>Mouth infection</b>	1 capsule once daily	15 days
* <b>Eye infection</b>	2 capsules once daily	21 days
* <b>Internal infection</b>	1 to 4 capsules daily	longer periods



* <b>Nail infection:</b> depending on your personal needs, your doctor will choose either continuous or cyclic therapy.										
<b>- Continuous therapy for toenail infection</b>		2 capsules once daily					3 months			
<b>- Cyclic nail therapy</b>		2 capsules twice daily					1 week			
		After that stop taking SPORAL for 3 weeks. Then the cycle is repeated, once for finger nail infections and twice for toe nail infections (with or without finger nail infections) (see table below)								
<b>Site of Infection</b>	<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	<b>Week 4</b>	<b>Week 5</b>	<b>Week 6</b>	<b>Week 7</b>	<b>Week 8</b>	<b>Week 9</b>	<b>Week 10</b>
<b>FINGER NAILS only</b>	Take 2 capsules twice daily	No SPORAL			Take 2 capsules twice daily	STOP				
<b>TOE NAILS with or without finger nails</b>	Take 2 capsules twice daily	No SPORAL			Take 2 capsules twice daily	No SPORAL			Take 2 capsules twice daily	STOP

**Skin infections:** With skin infections, the lesions will completely disappear a few weeks after the end of treatment with SPORAL capsules. This is typical of fungal patches: the drug kills the fungus itself, but the lesion disappears together with regrowth of healthy skin.

**Nail infections:** Nail lesions disappear 6 to 9 months after the end of treatment with SPORAL capsules since the drug kills only the fungus. 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.

**Infections of the internal organs:** higher doses with SPORAL capsules maybe be required for a longer duration.

Always stick to the instructions from your doctor, who may adapt the treatment to your personal needs.



## UNDESIRE D EFFECTS

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

- 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, chills, 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, increase in blood pressure, decrease in blood pressure, or heart failure may also occur. Changes in laboratory tests may occur such as decrease in granulocytes, decrease in white blood cells, decrease in platelets, decrease in blood magnesium, decrease in blood potassium, increase in blood potassium, increase in blood sugar, increase in blood creatine phosphokinase, increase in liver enzymes, increase in blood bilirubin, increase in blood triglycerides, or increase in blood urea.
- Hypersensitivity to SPORAL capsules can occur. It can be recognized, for instance, by skin rash, itching, hives, shortness of breath or difficulty breathing, and/or swollen face. Uncommonly, diminished sensation in the limbs, a tingling sensation in the limbs, or other problems with the nerves in the arms or legs can occur. Very rarely, an oversensitivity to sunlight, or a severe skin disorder (widespread rash with peeling skin and blisters in the mouth, eyes and genitals, or rash with small pustules or blisters) can occur.
- 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.



## OVERDOSE

Tell your doctor immediately if you have taken too much SPORAL. (S)he will take the necessary measures.



## HOW TO STORE SPORAL CAPSULES

Keep SPORAL below 30°C (this is at a normal room temperature).

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

Return old medicines to your pharmacist.



## WHAT IS IN SPORAL CAPSULES?

SPORAL capsules is a medicine used to treat fungal infections.

The active ingredient in SPORAL capsules is itraconazole.

SPORAL capsules comes in pink-blue capsules:

- 1 carton contains 1 blister. Each blister contains 4 capsules.
- 1 capsule contains 100 milligrams itraconazole;
- the capsules also contain hypromellose, macrogol, and sugar spheres.

Latest update of this package insert: **06-Oct-2023 (CPPI version 16-Feb-2023)**

***What you should know about medicines...***

*Always inform your doctor or pharmacist if you are using other medicines because some drugs should not be taken together.*

*It is important that you use medicines correctly. That is, you should:*

- always carefully read the full patient information leaflet;
- use medicines only for the purpose for which you were given the medicines;
- use medicines only in the prescribed amount;
- use medicines only for the prescribed period of time.

*Keep all medicines out of the reach of children.*

*Never allow others to use medicines recommended for you and never use medicines prescribed for others.*

*Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example!).*

*Return unused or old medicines to your pharmacist.*

*If someone has taken an overdose of a medicine, call a doctor or the poison control centre.*

**MARKETING AUTHORISATION NUMBER AND DATE OF AUTHORISATION**

<b>Manufactured by</b>	<b>Market Authorisation Number</b>	<b>Date of Authorisation</b>
Janssen Cilag SpA., Latina, Italy	1C 15010/64	18 March 2021

**Imported by**

Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at [aepqcjacth@its.jnj.com](mailto:aepqcjacth@its.jnj.com)

For any product information, please contact us at [medinfosea@its.jnj.com](mailto:medinfosea@its.jnj.com)

Please see full prescribing information at <https://ndi.fda.moph.go.th>