CANDIFORCE-100

Itraconazole/Itraconazole Capsules BP 100mg

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What Candiforce-100 is used for

Candiforce-100 capsules are used for infections caused by fungi or yeasts in adults.

They are used for:

- Infections of the mouth or vagina causing 'thrush'
- Skin infections
- Infections affecting other parts of the body

Patches of skin may take a few weeks to completely clear up after you have finished your treatment with Candiforce-100. Finger and toe nails may take several months to completely clear up. This is because your skin or nail will only look normal after new skin or nail has grown, even though the medicine has killed the fungus that caused the infection

How Candiforce-100 works

Candiforce-100 contains Itraconazole. This belongs to a group of medicines called 'antifungals'.

Candiforce-100 works by killing the fungus that caused the infection.

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

Before you use Candiforce-100

- *When you must not use it*

  - If you are allergic (hypersensitive) to Itraconazole.
  - If you are allergic (hypersensitive) to any of the other ingredients in this medicine.

Talk to your doctor or pharmacist before taking this medicines

- If you have ever had kidney problems. Your dose of Candiforce-100 may have to be changed
- If you have ever had liver problems such as yellow skin (jaundice). Your dose of Candiforce-100 may have to be changed. If after taking this medicine you have a severe lack of appetite, feel sick (nausea), are sick (vomiting), feel unusually tired, get stomach pain, muscle weakness, yellowing of the skin or whites of the eyes, unusually dark urine, pale stools or hair loss, stop taking Candiforce-100 and tell your doctor straight away
- If you have ever had a heart problem including heart failure (also called congestive heart failure or CHF). Candiforce-100 could make it worse. If after taking this medicine you get any of the following:
  - shortness of breath
  - unexpected weight gain
  - swelling of your legs or tummy
  - feel unusually tired
  - wake up short of breath at night

  Stop taking Candiforce-100 and tell your doctor straight away. These may be signs of heart failure
- If you have Acquired Immunodeficiency Syndrome (AIDS) or your immune system is not working as well as it should
- If you have had an allergic reaction to another antifungal product in the past

Children and the elderly

Candiforce-100 capsules are not normally given to children under the age of 12 or the elderly. However, your doctor may prescribe them in special cases.

Pregnancy and lactation

Please ask your doctor or pharmacist for advice before taking Candiforce-100:

- Do not take Candiforce-100 if you are pregnant unless your doctor has told you to. You should use contraception to make sure that you do not become pregnant when taking this medicine
- The medicine in Candiforce-100 stays in your body for some time after you have stopped taking them. After your treatment has finished, you must use contraception up until your next period (menstrual bleed). Ask your doctor for advice on what type of contraception to use
- If you become pregnant after starting a course of Candiforce-100, stop taking them and tell your doctor straight away
- Do not breast-feed if you are taking Candiforce-100, as small amounts of the medicine could pass into your milk. Ask your doctor for advice
- If you are breast-feeding

- *Before you start to use it*

  - Tell your doctor if you have allergies to any other medicines, foods , preservatives or dyes
  - Tell your doctor if you plan to become pregnant or breastfeeding.
  - Tell your doctor, if you are already taking any medicines.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular, do not take the following list of medicines with Candiforce-100 and tell your doctor if you are taking any of these:

- Medicines for hay fever or allergy called terfenadine, astemizole or mizolastine
- Medicines to lower cholesterol called lovastatin or simvastatin

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- Medicines for an irregular heart beat called quinidine, disopyramide, dronedarone or dofetilide
- Medicines used to treat angina (crushing chest pain) and high blood pressure called bepridil, felodipine, lercanidipine, ivabradine, ranolazine and nisoldipine
- Medicines for migraine headaches called dihydroergotamine and ergotamine.
- Medicines for the treatment of drug abuse called levacetylmethadol and methadone
- Cisapride - for digestive problems
- Colchicine (in patients with kidney and liver problems as well) – for gout
- Eplerenone – a diuretic
- Ergometrine (ergonovine) and methylergometrine (methylergonovine) - used after giving birth
- Halofantrine – for malaria
- Irinotecan – for cancer
- Midazolam (by mouth) or triazolam - for anxiety or to help you sleep
- Pimozide, lurasidone and sertindole - for conditions affecting thoughts, feelings and behaviour

Do not start taking Candiforce-100 and tell your doctor if you are taking any of the above. Also, upon completing your course of Candiforce-100, do not take any of the medicines listed above for 2 weeks.

Tell your doctor if you are taking the following medicines as they are not recommended with Candiforce-100 unless your doctor feels it is necessary.

- Medicines for the treatment of cancer called dasatinib, nilotinib and trabectedin
- Aliskiren – for high blood pressure
- Colchicine – for gout
- Everolimus – usually given after an organ transplant
- Fentanyl – a strong painkiller
- Rivaroxaban – a medicine to thin blood
- Salmeterol – for asthma and other breathing problems
- Tamsulosin - for urinary incontinence in men
- Vardenafil – for erection problems

Also, upon completing your course of Candiforce-100, do not take any of the medicines listed above for 2 weeks.

Do not take any of following medicines 2 weeks before and while you are taking Candiforce-100 unless your doctor tells you otherwise:

- Medicines for tuberculosis called rifampicin, rifabutin or isoniazid
- Medicines for epilepsy called carbamazepine, phenytoin or phenobarbital
- Medicines to treat viral infections called efavirenz or nevirapine

How to use Candiforce-100

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

Taking Candiforce-100:

- Always take Candiforce-100 straight after a meal as this helps your body to use the medicine
- Swallow the capsules whole with some liquid
- There must be enough acid in your stomach to make sure that your body can use the medicine. Medicines for indigestion, stomach ulcers or heartburn can affect the stomach producing acid. For this reason you should wait two hours after taking Candiforce-100 before taking any of these other medicines. If you do take medicines that stop the production of stomach acid, you should take Candiforce-100 with a drink of cola

- *How much to use*

Your doctor will tell you how much to take Candiforce-100.

- *When to use it*

Your doctor will tell you when to use Candiforce-100.

- *How long to use it*

Your doctor will tell you how many Candiforce-100 to take and for how long depending on your infection.

- *If you forget to use it*

- If you forget to take your capsules, take them as soon as you remember. However, if it is nearly time for the next capsules, skip the missed capsules.
- Do not take a double dose to make up for a forgotten dose.

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If you have further questions about using this medicine, please ask your doctor or pharmacist.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*

- Always take Candiforce-100 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- Please tell your doctor or pharmacist treating you that you are using Candiforce-100.
- Please tell your doctor immediately if you become pregnant while using this medicine.

- *Things you must not do*

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Candiforce-100 to anyone else, even if they have the

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same symptoms or condition as you.

- *Things to be careful of*

- Candiforce-100 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, Candiforce-100 can cause side effects although not everybody gets them.

Important side effects to look out for:

You must get urgent medical help if you have any of the following symptoms.

- Sudden signs of allergy such as rash, hives (also known as nettle rash or urticaria), severe irritation of your skin, swelling of the face, lips, tongue or other parts of the body. These may be signs of a severe allergic reaction. This only happens in a small number of people
- Severe skin disorders with peeling and/or rashes with small pustules (with a fever) or blistering of the skin, mouth, eyes and genitals, with fever, chills, aching muscles and generally feeling unwell. (This occurs rarely)
- A tingling sensation, numbness or weakness in your limbs. (This occurs rarely)
- Severe lack of appetite, feeling sick (nausea), being sick (vomiting), unusual tiredness, stomach pain, muscle weakness, yellowing of your skin or whites of your eyes (jaundice), unusually dark urine, pale stools or hair loss. These may be signs of a liver problem. (This only happens in a small number of people)
- Shortness of breath, unexpected weight gain, swelling of your legs or abdomen, feeling unusually tired or waking up short of breath at night. These may be signs of heart failure. Shortness of breath can also be a sign of fluid on the lungs. (This occurs rarely).
- Increased blood pressure, muscle weakness, swelling of legs, lethargy, lack of appetite, nausea, vomiting, headache, confusion, tingling, numbness.

Other possible side effects:

Common (affects less than 1 in 10 people)
- Stomach ache, feeling sick (nausea)
- Headache

Uncommon (affects less than 1 in 100 people)
- Problems with periods
- Sinusitis, runny nose, coughs and colds
- Constipation, diarrhoea, wind, being sick (vomiting), indigestion

Rare (affects less than 1 in 1000 people)
- Increases in liver function tests (shown by blood tests)
- Unexpected passing of urine or need to urinate (pass water) more often
- Problems with sight including blurred vision and double vision
- Change in taste
- Certain blood disorders which may increase the risk of infections
- Ringing in your ears
- Hearing loss (may be permanent)
- Severe upper stomach pain, often with nausea and vomiting (inflammation of the pancreas)
- Swelling due to fluid under the skin
- Unusual hair loss or thinning (alopecia)
- High levels of triglycerides in the blood (shown by blood tests)
- Red, itchy, flaking or peeling skin
- Sensitivity of the skin to light
- Erection difficulties

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

Storage and Disposal of Candiforce-100

- *Storage*

- Keep out of the reach of children.
- Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month
- Store below 30°C. Protect from light & moisture

- *Disposal*

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need any more. If you do this you will help protect the environment.

Product Description

- *What it looks like*
Size "0el" hard gelatin white opaque capsules filled with off white to cream colored pellets.
Candiforce-100 is supplied in blister packs of 30 capsules

- *Ingredients*
  - *Active ingredient*
- Itraconazole Ph. Eur. - 100 mg (As Itraconazole Pellets)

  - *Inactive ingredients*

- Sugar Spheres, Hypromellose, Polyethylene Glycol, Methylene Chloride, Dehydrated Alcohol (Ethanol).
- Capsule Shell: Gelatin, Titanium Dioxide

Important information about some of the ingredients of Candiforce-100:

Candiforce-100 contains:
Sugar: If your doctor has told you that you are intolerant of some sugars, contact them before taking this medicine.

Please ask your doctor if you are worried about any of the ingredients in this medicine.

- *MAL number:*
  MAL20076044ACZ

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