

PATIENT INFORMATION LEAFLET**Scheduling status**

S4

INCRAFLO 20 mg, film-coated tablets

Tadalafil

Contains sugar: lactose 249,00 mg

Read all of this leaflet carefully before you start taking INCRAFLO 20 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- INCRAFLO 20 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What INCRAFLO 20 mg is and what it is used for.
2. What you need to know before you take INCRAFLO 20 mg.
3. How to take INCRAFLO 20 mg.
4. Possible side effects.
5. How to store INCRAFLO 20 mg.
6. Contents of the pack and other information.

1. What INCRAFLO 20 mg is and what it is used for

The active ingredient in INCRAFLO 20 mg tablets is tadalafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

INCRAFLO 20 mg helps increase blood flow to the penis and may help men with erectile dysfunction get and keep an erection satisfactory for sexual activity. Once a man has completed sexual activity, blood flow to his penis decreases, and his erection goes away.

2. What you need to know before you take INCRAFLO 20 mg

Do not take INCRAFLO 20 mg

- if you are allergic (hypersensitive) to tadalafil or to any of the tablet ingredients listed in section 6.
- if you take any medicines called nitrates (used in the treatment of angina).
- if you have a serious heart disease or had a heart attack within the last 90 days.
- if you had a stroke within the last 6 months.
- if you have chest pains during or after sexual activity, have abnormal heart rhythm or heart failure.
- if you have low blood pressure or uncontrolled high blood pressure.
- if you have severe liver disease.
- if you are also using any of the following medicines: azole antifungals such as ketoconazole, itraconazole, voriconazole, ritonavir and other protease inhibitors.
- if you have had previous experience of a decrease or loss of hearing in one or both ears, with or without dizziness.
- if you have ever had severe vision loss, including a condition called NAION.
- if you are taking any guanylate cyclase stimulators such as riociguat. This group of medicines is used to treat pulmonary hypertension. INCRAFLO 20 mg used together with these medicines may cause low blood pressure.

Warnings and precautions

Take special care with INCRAFLO 20 mg

Tell your doctor if you have a history of heart disease. Be aware that sexual activity carries a possible risk to patients with heart disease because it puts extra strain on your heart.

You should NOT use nitrates if you experience chest pain during or after sexual activity, but rather seek immediate medical assistance.

If you experience long erections lasting 4 hours or more, talk to your doctor immediately as this can result in permanent tissue damage.

Before taking INCRAFLO 20 mg, tell your doctor:

- if you have sickle cell anaemia (an abnormality of red blood cells)
- if you have multiple myeloma (cancer of the bone marrow)
- if you have leukemia (cancer of the blood cells)
- if you use other treatments for erectile dysfunction
- if you have a deformed penis shape or Peyronie's disease
- if you have a serious liver problem
- if you have kidney problems or require dialysis.

INCRAFLO 20 mg is not intended for use by women or by children or adolescents under the age of 18.

Other medicines and INCRAFLO 20 mg

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor before taking INCRAFLO 20 mg if you are already taking any of the following medicines:

- nitrates (used in the treatment of angina (chest pains))
- medicines to treat high blood pressure (hypertension)
- ketoconazole and itraconazole (used to treat fungal infections)
- ritonavir, saquinavir (used in the treatment of HIV/AIDS)
- rifampicin (used to treat tuberculosis)
- antacids (used to neutralize acid in the stomach)
- riociguat (used to treat pulmonary hypertension)
- clarithromycin, telithromycin, erythromycin (antibiotics)
- other medicines or treatments for erectile dysfunction.

Taking INCRAFLO 20 mg with food and drink

INCRAFLO 20 mg can be taken any time of the day with or without food.

Pregnancy and breastfeeding

INCRAFLO 20 mg is not indicated for use by women.

Driving and using machines

Patients should be aware of how they react to INCRAFLO 20 mg before driving or operating heavy machinery.

It is not always possible to predict to what extent INCRAFLO 20 mg may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which INCRAFLO 20 mg affects you.

Important information about some of the ingredients of INCRAFLO 20 mg

INCRAFLO 20 mg contains lactose (a milk sugar). If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.

3. How to take INCRAFLO 20 mg

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

Always take INCRAFLO 20 mg exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

INCRAFLO 20 mg tablets are for oral use. Swallow the tablet whole with some water. You may take INCRAFLO 20 mg with or without food.

Take one INCRAFLO 20 mg tablet before you expect to have sexual activity.

You may take a INCRAFLO 20 mg tablet at least 16 minutes before sexual activity. INCRAFLO 20 mg may still be effective up to 36 hours after taking the tablet. It is important to note that INCRAFLO 20 mg does not work if there is no sexual stimulation.

Do not take INCRAFLO 20 mg more than once a day. INCRAFLO 20 mg is intended for use prior to anticipated sexual activity and is not recommended for continuous daily use.

Your healthcare provider may change your dose of INCRAFLO 20 mg depending on how you respond to the medicine, and on your health condition.

If you have the impression that the effect of INCRAFLO 20 mg is too strong or too weak, talk to your doctor or pharmacist.

If you take more INCRAFLO 20 mg than you should

Do not take more than one dose per day.

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

If you forget to take INCRAFLO 20 mg

Do not take a double dose to make up for a forgotten tablet. You should not take INCRAFLO 20 mg more than once a day.

4. Possible side effects

INCRAFLO 20 mg can have side effects.

Not all side effects reported for INCRAFLO 20 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking INCRAFLO 20 mg, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking INCRAFLO 20 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty breathing
- Severe skin rash or itching
- Swollen tongue or lips

These are all very serious side effects. If you have them, you may have had a serious reaction to INCRAFLO 20 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain
- An erection that lasts longer than 4 hours
- Sudden loss of vision

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache

- facial flushing (redding of the face)
- stuffy or runny nose
- indigestion
- back pain
- muscle aches
- pain in arms and legs.

Less frequent side effects:

- Dizziness
- Loss of consciousness or numbness on one side of the body
- Fainting, severe headache (migraine), sudden memory loss
- Blurred vision or loss of vision, eye pain, swelling of eyelids, redness or itching of the eye
- Ringing in ears, loss of hearing
- Changes in heart rhythm, chest pain or feeling of pressure in chest
- Low or high blood pressure
- Difficulty breathing, nose bleeds
- Stomach pain, nausea, vomiting, heartburn or burning sensation in your throat
- Rash, sweating
- Blood in urine
- Prolonged erections, blood in the sperm or bleeding from the penis
- Chest pain, tiredness, swelling of the legs or face

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8> .

By reporting side effects, you can help provide more information on the safety of INCRAFLO 20.

5. How to store INCRAFLO 20 mg

Store all medicines out of reach of children.

Store at or below 30 °C, in the original package. Keep blisters in the carton until required for use.

Do not use INCRAFLO 20 mg after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What INCRAFLO 20 mg contains

The active substance is tadalafil 20 mg.

The other ingredients are:

Lactose, microcrystalline cellulose, hydroxypropylcellulose, sodium lauryl sulphate, croscarmellose sodium, magnesium stearate, Opadry II 32K520009 Yellow.

What INCRAFLO 20 mg looks like and contents of the pack

INCRAFLO 20 mg tablets are yellow coloured, almond shaped, film coated tablets, debossed with “20” on one side and plain on other side.

The film-coated tablets are packed in PVC/PVDC/Aluminium foil blisters strips containing 1, 2, 4 or 10 tablets. The blister strips are packed in cartons.

Not all packs may be marketed.

Holder of certificate of registration

Smart Pharmaceuticals (Pty) Ltd

247 Voortrekker Road

Kraaifontein, Cape Town

7800

This leaflet was last revised in

To be allocated

Registration number

48/7.1.5/0034