

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

INNOPECIA 1mg: Each Film-coated Tablet contains finasteride.

Contains: Sugar (Lactose 87.8 mg)

For full list of excipients: **see section 6.**

Read all this leaflet carefully before you start taking INNOPECIA

What is in this leaflet

1. What **INNOPECIA** is and what it is used for
2. What you need to know before you take **INNOPECIA**
3. How to take **INNOPECIA**
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1. What **INNOPECIA** is and what is it used for:

INNOPECIA is a type of medicine called "Type II 5-alpha reductase inhibitors".

INNOPECIA is used for the treatment of male pattern hair loss (=also known as androgenic alopecia). **INNOPECIA** increases hair growth on the scalp and prevents further hair loss in men between the ages of 18 to 41 years.

2. What you need to know before you take **INNOPECIA**:

Do not take **INNOPECIA**:

- If you are allergic to finasteride or any of the other ingredients of **INNOPECIA** (listed in section 6).
- If you are a woman, including during pregnancy.
- If you are under 18 years of age
- If you are pregnant or may become pregnant. **INNOPECIA** may harm your unborn baby:
 - **INNOPECIA** tablets are coated and will prevent contact with the medicine during handling, as long as the tablets are not broken or crushed. Females who are pregnant or who may become pregnant should not come in contact with broken or crushed **INNOPECIA** tablets. If a pregnant woman comes in contact with crushed or broken **INNOPECIA** tablets, wash the contact area right away with soap and water. If a woman who is pregnant comes into contact with the active ingredient in **INNOPECIA**, a healthcare provider should be consulted.

- If a woman who is pregnant with a male baby swallows or comes in contact with the medicine in **INNOPECIA**, the male baby may be born with sex organs that are not normal.
- If you are already taking finasteride or dutasteride (used for a prostate problem called benign prostatic hyperplasia (BPH)).

Warnings and precautions

Take special care with **INNOPECIA**:

- If you have other medical conditions, including problems with your prostate.
- Mood alterations and depression
 - Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with Finasteride. If you experience any of these symptoms stop taking **INNOPECIA** and contact your doctor for further medical advice as soon as possible.
- Effects on Prostate Specific Antigen (PSA)
 - **INNOPECIA** can affect a blood test called PSA (Prostate-Specific Antigen) for the screening of prostate cancer. If you have a PSA test done you should tell your doctor or pharmacist that you are taking **INNOPECIA** because **INNOPECIA** decreases PSA levels.
- Effects on fertility

- Infertility has been reported in men who took **INNOPECIA** for long time and had other risk factors that may affect fertility. Normalisation or improvement of seminal quality has been reported after discontinuation of **INNOPECIA**. Long-term clinical studies about the effect of **INNOPECIA** on fertility in men have not been conducted.
- Effects on liver
 - A range conditions caused by a build-up of fat in the liver. (Non-alcoholic fatty liver disease (NAFLD)).

Children and adolescents:

INNOPECIA should not be used in children and adolescents below 18 years.

Other medicines and INNOPECIA:

Always tell your health care provider if you are taking any other medicines. This includes all complementary or traditional medicines.

- Do not take **INNOPECIA** if you are already taking finasteride or dutasteride, used for a prostate problem called benign prostatic hyperplasia (BPH).

INNOPECIA with food, drink, and alcohol:

INNOPECIA can be administered irrespective of whether food is taken or not.

Pregnancy and breastfeeding and fertility:

If you are pregnant or may become pregnant. **INNOPECIA** may harm your unborn baby:

INNOPECIA tablets are coated and will prevent contact with the medicine during handling, as long as the tablets are not broken or crushed. Females who are pregnant or who may become pregnant should not come in contact with broken or crushed **INNOPECIA** tablets. If a pregnant woman comes in contact with crushed or broken **INNOPECIA** tablets, wash the contact area right away with soap and water. If a woman who is pregnant comes into contact with the active ingredient in **INNOPECIA**, a healthcare provider should be consulted.

INNOPECIA is contraindicated in women due to the risk of pregnancy. Tell your doctor if you are pregnant or breastfeeding:

- **INNOPECIA** tablets should not be used during pregnancy.

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 health care provider for advice before taking this medicine.

Driving and using machines:

INNOPECIA is not likely to affect you being able to drive, use tools or machines.

It is not always possible to predict to what extent **INNOPECIA** 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 **INNOPECIA** affects them.

INNOPECIA contains: Lactose

INNOPECIA contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take INNOPECIA:

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

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

The usual dose is:

Adults:

The usual dose for adults is one 1 mg **INNOPECIA** tablet daily.

In general, daily use for at least 3 months is necessary before increased hair growth and/or prevention of further hair loss is noticeable.

Your doctor will tell you how long your treatment with **INNOPECIA** will last. Do not stop treatment early. If you have the impression that the effect of **INNOPECIA** is too strong or too weak, tell your doctor or pharmacist.

If you take more INNOPECIA than you should:

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

If you forget to take a dose of INNOPECIA:

If you have missed a dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **INNOPECIA** at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking INNOPECIA:

Continued use is recommended for maximum benefit. Effects of the tablet may be reversed within 12 months after you stop treatment.

4. Possible side effects

INNOPECIA can have side effects.

Not all side effects reported for **INNOPECIA** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **INNOPECIA**, please consult your health care provider for advice.

Stop taking **INNOPECIA** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing',
- rash or itching',
- fainting'

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

hospitalisation.

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

- Decrease in your blood Prostate Specific Antigen (PSA) levels. **INNOPECIA** can affect a blood test called PSA (Prostate-Specific Antigen) for the screening of prostate cancer. If you have a PSA test done you should tell your healthcare provider that you are taking **INNOPECIA** because **INNOPECIA** decreases PSA levels. Changes in PSA levels will need to be evaluated by your healthcare professional. Any increase in follow-up PSA levels from their lowest point may signal the presence of prostate cancer and should be evaluated, even if the test results are still within the normal range for men not taking **INNOPECIA**. You should also tell your healthcare provider if you have not been taking **INNOPECIA** as prescribed because this may affect the PSA test results.

These are all profoundly serious side effects. If you have them, you may have had a serious reaction to **INNOPECIA**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- trouble getting or keeping an erection
- a decrease in the amount of semen

Less frequent side effects:

- Breast tenderness and enlargement. Tell your healthcare provider about any changes in your breasts such as lumps, pain or nipple discharge.
- Depression.
- Decrease in sex drive that continued after stopping **INNOPECIA**.
- Allergic reactions including rash, itching, hives and swelling of the lips, tongue, throat, and face.
- Problems with ejaculation that continued after stopping **INNOPECIA**.
- Testicular pain.
- Difficulty in achieving an erection that continued after stopping the medication.
- Male infertility and/or poor quality of semen.
- Less frequent rare cases, male breast cancer
- decrease in sex drive
- Blood in semen
- Fast heartbeat
- Elevated liver enzymes
- Anxiety

Frequent Unknown side effects:

- A range conditions caused by a build-up of fat in the liver. (Non-alcoholic fatty liver disease (NAFLD)).

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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 or 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 : https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf. By reporting side effects, you can help provide more information on the safety of **INNOPECIA**.

5. How to store INNOPECIA

INNOPECIA should be stored in the original packaging (keep blisters in the carton until required for use).

Store at or below 25 °C.

Protect from moisture and sunlight.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

Do not use after the expiry date stated on the label and carton.

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 INNOPECIA contains:

The active substance in **INNOPECIA** is finasteride.

The other ingredients are cellulose microcrystalline, docusate sodium, lactose monohydrate, magnesium stearate, opadry brown, starch pregelatinised, sodium starch glycolate.

INNOPECIA contains: Sugar (Lactose)

What INNOPECIA looks like and contents of the pack

INNOPECIA 1 mg: Brown colour, round film coated tablets, debossed with 'H' on one side and '36' on the other side.

Holder of Certificate of Registration

Innovata Pharmaceuticals

Crownwood Office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

South Africa

This leaflet was revised in

Applicant/PHCR: *Innovata Pharmaceuticals (Pty) Ltd*
Product Proprietary Name: *Innopecia 1 mg.*
Dosage Form & Strength: *Film-coated Tablets, finasteride 1 mg.*

CTD, Module

30 October 2023

Registration number

A 50/21.12/0579

Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **INNOPECIA**.