APPROVED PATIENT INFORMATION LEAFLET

S4

AUROGRA (film-coated tablet)

Dolutegravir

Read all of this leaflet carefully before you start taking

AUROGRA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AUROGRA** has been prescribed for you personally and you should not share your medicine with other people. It may harm

1. WHAT AUROGRA CONTAINS:

The active ingredient is 50 mg of dolutegravir.

The other ingredients of **AUROGRA** microcrystalline cellulose, Opadry II brown 85F565096, povidone, sodium starch glycolate and sodium stearyl fumarate.

In addition, the coating material Opadry II brown 85F565096 contains iron oxide (C.I. No: 77491), polyethylene glycol 3350, polyvinyl alcohol, talc and titanium dioxide (C.I. No: 77891).

Contains sugar: 145.40 mg mannitol.

2. WHAT AUROGRA IS USED FOR:

AUROGRA is a type of medicine known as an anti-retroviral (ARV).

It belongs to a group of medicines called integrase inhibitors (INIs).

AUROGRA is used to treat HIV (human immunodeficiency virus) infection in adults aged 18 years and older.

AUROGRA is also used in combination therapy (i.e., **AUROGRA** with other anti-retroviral medicines).

3. BEFORE YOU TAKE AUROGRA:

Do not take AUROGRA:

- If you are hypersensitive (allergic) to dolutegravir or any of the other ingredients of **AUROGRA**.
- If you are already treated by the medicines called dofetilide or pilsicainide (this medicines are used to treat abnormal rate of muscle contractions in the heart).
- If you are treated by a medicine called metformin (this medicine is used for diabetes - lowering of sugar levels in the body).
- If you have any liver disease (mild to moderate).

Take special care with AUROGRA:

Tell your doctor

- If you get any rash as it may be an indication that you are having an allergic reaction. You should stop taking **AUROGRA** and contact your doctor immediately if you get other symptoms of an allergic reaction such as fever, fatigue, muscle or joint aches, blisters, sores in your mouth, swelling of your feet or face.
- If you get any other symptoms of other serious infections, usually due to your already weakened immune system. When you start treatment you may find that old, hidden infections (such as tuberculosis) flares up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight against these infections.
- If you notice that there is a change in the distribution of fat throughout your body e.g. a hump forming on your back, loss of fat from your face, collection of fat around your abdomen.
- If you experience joint aches and pains, stiffness in your joints or any difficulty with movement, it may be an indication that your bones are being damaged.
- If you are taking any other medicines even if they are non-prescription.

However do not stop taking **AUROGRA** without your doctor’s advice.

- **AUROGRA** does not cure HIV infection, it only reduces the amount of virus in your blood

  therefore HIV can still be transmitted while you are taking **AUROGRA**. You should therefore use condoms during intercourse.

Taking AUROGRA with food and drink:

AUROGRA can be taken with or without food.

Pregnancy and Breastfeeding:

If you are pregnant, or think you could be, or if you are planning to have a baby,don't take AUROGRA. without checking with your doctor. Your doctor will consider the benefit to you and the risk to your baby of taking AUROGRA. while you're pregnant.

If you could get pregnant while receiving AUROGRA., you need to use a reliable method of contraception, to prevent pregnancy.

It is not recommended to breastfeed your baby if you are HIV positive as HIV infection may be transmitted through the breast milk.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **AUROGRA**.

Driving and using machinery:

After taking **AUROGRA** you may get dizzy therefore do not drive or operate machinery unless you know what the effect of **AUROGRA** is on you.

Important information about some of the ingredients of AUROGRA:

AUROGRA contains mannitol and may have a laxative effect.

Taking other medicines with AUROGRA:

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

Do not take AUROGRA with the following medicines:

- Dofetilide or pilsicainide used to treat heart conditions,
- Metformin, which is used to treat diabetes.

AUROGRA may have an effect on other medicines or other medicines may have an effect on **AUROGRA** thus causing you to have side effects.

Tell your doctor if you are taking any of the following medicines:

- Medicines used to treat indigestion and heartburn called antacids should only be taken at least 6 hours before you take **AUROGRA** or 2 hours after taking **AUROGRA**.
- Calcium and iron supplements should also only be taken at least 6 hours before you take **AUROGRA** or 2 hours after taking **AUROGRA**.
- Etravirine, efavirenz, nevirapine, tipranavir/ritonavir, fosamprenavir/ ritonavir which are all used in the treatment of HIV infection.
- Rifampicin which is used to treat tuberculosis.
- Phenytoin and phenobarbital which is used to treat epilepsy.
- Oxcarbamazepine and carbamazepine used to treat epilepsy and bipolar disorder.
- St. John's wort, a herbal remedy for depression.

You should tell your doctor or pharmacist if you are taking any of these medicines. Your doctor will then decide to adjust your dose if required.

4. HOW TO TAKE AUROGRA:

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

Always take **AUROGRA** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose of **AUROGRA** is one 50 mg tablet, once a day.

Your doctor will however decide on the best dose of **AUROGRA** for you.

Your doctor will tell you how long your treatment with **AUROGRA** will last. If you have the impression that the effect of **AUROGRA** is too strong or too weak, tell your doctor or pharmacist.

If you take more AUROGRA than you should:

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

If you forget to take AUROGRA:

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBILE SIDE EFFECTS:

AUROGRA can have side effects.

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

If any of the following happens, stop taking **AUROGRA** and tell your doctor immediately or go to the casualty department at your nearest hospital.

- skin rash,
- fever,
- lack of energy,
- swelling of the face and mouth causing difficulty in breathing,
- muscle or joint aches.
- IRIS (development of other inflammatory reactions or infections when you begin treatment with **AUROGRA.**

These are very serious side effects therefore you should see your doctor as soon as possible or go to your nearest hospital.

The following side effects occur frequently:

- insomnia (difficulty in sleeping),
- headache,
- dizziness,
- abnormal dreams,
- nausea,
- diarrhoea (frequent and watery bowel movements),
- vomiting,
- flatulence (excessive gas/ wind),
- upper abdominal pain,
- pruritus (an intense itching sensation),
- fatigue (temporary loss of strength and energy),
- depression.

The following side effects occur less frequently:

- abdominal pain,
- abdominal discomfort.
- allergic reactions,
- inflammation of the liver usually noticed by yellowing of your skin and nails,
- suicide attempts or thoughts about suicide.

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

6. STORING AND DISPOSING OF AUROGRA:

Store at or below 30 °C.

Keep HDPE containers tightly closed. Keep the HDPE container in the pre-printed carton which contains the professional information.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF AUROGRA:

HDPE Container pack:

Tablets are packed in white opaque round 60 ml HDPE container of 33 mm neck finish closed with white opaque 33 mm- 400 child resistance polypropylene closure with wad having induction sealing liner. Each HDPE container is packaged in an outer cardboard carton.

Pack size:

30's - One HDPE container contains 30 tablets.

8. IDENTIFICATION OF AUROGRA:

Reddish brown coloured, round, biconvex, film-coated tablets debossed with 'T over 50' on one side and plain on the other side.

9. REGISTRATION NUMBER:

51/20.2.8/0915.913.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Aurobindo Pharma (Pty) Ltd

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