1.3.2.1 Clean Patient Information Leaflet

SCHEDULING STATUS

S4

TOBI® 300 mg/5 ml, nebuliser solution

Tobramycin

Read all of this leaflet carefully before you start using TOBI

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.

TOBI 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 TOBI is and what it is used for

What TOBI is:

TOBI contains an antibacterial medicine called tobramycin (an aminoglycoside).

For full list of excipients see section 6.

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What it is used for:

TOBI is used for long-term management of chronic lung infection due to *Pseudomonas aeruginosa* in cystic fibrosis (CF) patients aged 6 years and older.

Cystic fibrosis is an inherited disease, primarily affecting the digestive and respiratory systems.

2. What you need to know before you use TOBI

Do not use TOBI:

- if you are hypersensitive (allergic) to tobramycin or any other aminoglycoside antibacterial or to any of the other ingredients of TOBI (*listed in section 6)*;
- if you are pregnant and breastfeeding.

Warnings and precautions

Take special care with TOBI if you:

- have or have had hearing problems (including noises in your ears such as ringing or hissing);
- have dizziness;
- have or have had kidney problems;
- have or have had problems with muscle weakness such as myasthenia gravis or Parkinson's disease;
- have or have had breathing problems such as wheezing, coughing, or chest tightness;
- are receiving aminoglycoside antibacterial treatment by injection or through a vein (intravenous) while using TOBI.

Children/ and adolescents:

TOBI is not recommended for use in children younger than 6 years of age.

Other medicines and TOBI

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

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

- other medicines that may harm your nervous system, kidneys, or hearing;
- “water pills” (diuretics) such as ethacrynic acid, furosemide, intravenous mannitol or urea.

Before you begin using any new medicine (prescription or non-prescription) or if you develop any new medical problem while you are using this medicine, check with your doctor, healthcare professional or pharmacist.

Pregnancy and breastfeeding and fertility

You should not take TOBI if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking TOBI.

Driving and using machinery

It is not always possible to predict to what extent TOBI may interfere with the daily activities of a patient. TOBI can cause a ringing or buzzing noise in one or both ears that may be constant or come and go, often associated with hearing loss or can cause dizziness.

Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TOBI affects them.

3. How to use TOBI

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

Always use TOBI exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Therapy should be initiated by a doctor experienced in the management of cystic fibrosis.

TOBI is supplied for use via inhalation and is not for parenteral use.

The usual dose is:

- The recommended dose for adults and children is one ampoule twice daily for 28 days.
- The dose interval should be as close as possible to 12 hours and not less than 6 hours.
- After 28 days of therapy, patients should stop TOBI therapy for the next 28 days. A cycle of 28 days of active therapy and 28 days of rest from treatment should be maintained.
- Your doctor will tell you how long your treatment with TOBI will last.

Method of administration:

- The contents of one ampoule should be emptied into the nebuliser and administered by inhalation over approximately a 15-minute period using a hand-held PARI LC PLUS reusable nebuliser with a suitable compressor.
- Suitable compressors are those which, when attached to a PARI LC PLUS nebuliser, deliver a flow rate of 4-6 L/min and/or a back pressure of 110-217 kPa.
- The manufacturers' instructions for the care and use of the nebuliser and compressor should be followed.

- TOBI is inhaled whilst the patient is sitting or standing upright and breathing normally through the mouthpiece of the nebuliser.
- Nose clips may help the patient breathe through the mouth.
- The patient should continue their standard regimen of chest physiotherapy.
- The use of appropriate bronchodilators should continue as thought clinically necessary. Where patients are receiving several different respiratory therapies, it is recommended that they are taken in the following order: bronchodilator, chest physiotherapy, other inhaled medicinal products, and finally TOBI.

It is very important that your doctor check your progress at regular visits to make sure that TOBI is working properly and to check for unwanted effects. Your doctor may also do hearing, kidney function or neuromuscular function checks.

If you have the impression that the effect of TOBI is too strong or too weak, tell your doctor or pharmacist.

If you use more TOBI 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 missed a dose of TOBI

If you forget to take TOBI and there are at least 6 hours to your next dose, take your dose as soon as you can.

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

4. Possible side effects

TOBI can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing;
- shortness of breath with wheezing;
- coughing and chest tightness;
- rash or itching;
- coughing up blood;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TOBI. 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:

- Hearing loss or ringing in the ears (ototoxicity). Tell your healthcare provider right away if you have hearing loss or you hear noises in your ears such as ringing or hissing. Tell your healthcare provider if you develop a sensation of spinning, difficulty with balance or dizziness.
- worsening kidney problems (nephrotoxicity) with symptoms such as collection of fluid in the body causing swelling in legs, ankles and feet. TOBI is in a class of medicine which may cause worsening kidney problems, especially in people with known or suspected kidney problems. Your healthcare provider may do a blood test to check

how your kidneys are working while you are using TOBI.

- worsening muscle weakness (neuromuscular disorder). TOBI is in a class of medicine which can cause muscle weakness to get worse in people who already have problems with muscle weakness (myasthenia gravis or Parkinson's disease).

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Increased cough;
- sore throat;
- increased sputum;
- discoloured sputum
- voice changes or loss or change in taste;
- runny nose;
- inflammation of the voice box;
- inflammation of the lungs;
- a general feeling of being ill or having no energy.

The following side effects have been reported less frequently:

- Fever;
- headache, pain;
- abdominal pain;
- fungal infection;
- back pain;
- nausea, loss of appetite;

- mouth sores, mouth infections;
- vomiting, diarrhoea;
- disorders of lymph nodes or lymph vessels (ailment of the delicate tubes throughout the body);
- dizziness;
- sleepiness;
- voice alteration (including hoarseness);
- nose bleeds;
- hyperventilation, oxygen deficiency;
- sinusitis (inflammation of the nasal passage);
- ear disorder, ear pain.

The following side effects have been reported but the frequency is unknown:

- Loss of voice;
- taste perversion (an altered or impaired sense of taste).

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

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

5. How to store TOBI

- Store at 2 - 8 °C.
- DO NOT FREEZE.
- Store in the original package in order to protect from light.
- After removal from the refrigerator, or if refrigeration is unavailable, TOBI pouches (intact or opened) may be stored at up to 25 °C for up to 28 days.
- TOBI solution is slightly yellow, but some variability in colour may be observed, which does not indicate loss of activity if the product has been stored as recommended.
- Store all medicines out of reach of children.
- Keep the container tightly closed.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- 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 TOBI contains:

The active substance is tobramycin.

The other ingredients are sodium chloride, sodium hydroxide for pH adjustment, sulphuric acid and water for injection.

What TOBI looks like and contents of the pack:

What TOBI looks like:

Clear slightly yellow solution.

Contents of the pack:

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TOBI is supplied in 5 ml single-use low density polyethylene ampoules in packs of 56.

Holder of Certificate of Registration and Manufacturer

Viatris South Africa (Pty) Ltd

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Isando

Republic of South Africa

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.