Approved Patient Information Leaflet for Medicines for Human Use

SCHEDULING STATUS: S4

SPIRODISC 50/100, 50/250 and 50/500, powder for inhalation

Salmeterol and fluticasone propionate

Contains sugar (lactose monohydrate)

Each dose of SPIRODISC 50/100 contains 13,127 mg of lactose (as monohydrate).

Each dose of SPIRODISC 50/250 contains 12,877 mg of lactose (as monohydrate).

Each dose of SPIRODISC 50/500 contains 12,627 mg of lactose (as monohydrate).

Read all of this leaflet carefully before you start using your SPIRODISC.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SPIRODISC 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 SPIRODISC is and what it is used for
2. What you need to know before you use SPIRODISC
3. How to use SPIRODISC
4. Possible side effects
5. How to store SPIRODISC
6. Contents of the pack and other information

1. What SPIRODISC is and what it is used for

SPIRODISC contains two medicines, salmeterol and fluticasone propionate:

- salmeterol is a long-acting bronchodilator which will help the airways in your lungs to stay open. This makes it easier for air to get in and out. The effects last for at least 12 hours.
- fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

The doctor has prescribed SPIRODISC for you to help prevent breathing problems such as:

- asthma
- Chronic Obstructive Pulmonary Disease (COPD).

You must use SPIRODISC every day as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD.

SPIRODISC helps to stop breathlessness and wheeziness coming on. However, SPIRODISC should not be used to relieve a sudden attack of breathlessness or wheezing. If this happens you need to use a fast-acting ‘reliever’ (‘rescue’) inhaler, such as salbutamol. You should always have your fast-acting ‘rescue’ inhaler with you.

2. What you need to know before you use SPIRODISC

Do not use SPIRODISC

- if you are hypersensitive (allergic) to salmeterol, fluticasone propionate or the other ingredient of SPIRODISC, lactose monohydrate.

Warnings and precautions

Take special care with SPIRODISC if you:

- have heart disease, including an irregular or fast heart beat
- have an overactive thyroid gland
- have high blood pressure
- have diabetes mellitus (your blood sugar may be increased while on SPIRODISC)
- have low potassium in the blood
- have or have had tuberculosis (TB), or other lung infections
- develop pneumonia (infection of the lung or lungs). You may notice that you have a fever or chills, increased mucous production, change in mucous colour or increased cough or increased breathing difficulties.

Contact your doctor if you experience:

- blurred vision or other visual disturbances
- if you find that your asthma is worsening or you are using your 'rescue' inhaler more often than you used to.
- If you notice a change in your body shape (weight gain especially accumulation of fat in the back, roundness of the face, increase in hair on the body and thinning of the bones)
- if you are planning to undergo surgery, inform your doctor that you are taking SPIRODISC.

Children and adolescents

SPIRODISC can cause the growth of some children to be slower than normal. Your doctor will periodically measure the height of your child to monitor this.

Other medicines and SPIRODISC

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

In particular, tell your doctor if you are using medicines containing any of the following:

- beta blockers (such as atenolol, propranolol and sotalol). These are medicines used to treat high blood pressure or other heart conditions
- medicines to treat infections (such as ketoconazole, itraconazole and erythromycin) including some medicines for HIV treatment (such as ritonavir). Some of these medicines may increase the amount of fluticasone propionate or salmeterol in your body. This can increase your risk of experiencing side effects with SPIRODISC, including irregular heartbeats, or may make side effects worse. Your doctor may wish to monitor you carefully if you are taking these medicines
- corticosteroids (by mouth or by injection). If you have had these medicines recently, this might increase the risk of SPIRODISC affecting your adrenal gland
- diuretics, also known as ‘water tablets’. These are medicines used to treat high blood pressure
- other bronchodilators (such as salbutamol)
- xanthine medicines (such as theophylline). These are medicines often used to treat asthma.

Pregnancy and breastfeeding

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.

The safety of SPIRODISC in pregnancy and breastfeeding has not been established.

Driving and using machines

SPIRODISC is not likely to affect your ability to drive or use machines.

It is not always possible to predict to what extent SPIRODISC may interfere with your daily activities. Do not drive or use machines until you are aware of the measure to which SPIRODISC affects you.

SPIRODISC contains lactose monohydrate

SPIRODISC contains up to 13,127 milligrams of lactose monohydrate in each dose. The amount of lactose in SPIRODISC does not normally cause problems in people who are lactose intolerant. The excipient lactose monohydrate contains small amounts of milk proteins, which may cause allergic reactions.

3. How to use SPIRODISC

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

Always use SPIRODISC exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

- Use your SPIRODISC every day until your doctor advises you to stop. Do not take more than the recommended dose. Check with your doctor or pharmacist if you are not sure.
- Do not stop taking SPIRODISC or reduce the dose of SPIRODISC without talking to your doctor first.
- SPIRODISC should be inhaled through the mouth into the lungs.

The usual dose is:

For asthma

Adults and adolescents aged 12 years and over:

- SPIRODISC 50/100: One inhalation twice a day or
- SPIRODISC 50/250: One inhalation twice a day or

- SPIRODISC 50/500: One inhalation twice a day.

Children 4 to 12 years of age:

- SPIRODISC 50/100: One inhalation twice a day

SPIRODISC is not recommended for use in children below 4 years of age.

For adults with Chronic Obstructive Pulmonary Disease (COPD)

- SPIRODISC 50/250 or SPIRODISC 50/500: One inhalation twice a day

Your doctor will tell you how long your treatment with SPIRODISC will last. Do not stop treatment early because this could make your breathing worse.

If your asthma or breathing gets worse tell your doctor straight away. You may find that you feel more wheezy, your chest feels tight more often or you may need to use more of your fast-acting 'reliever' medicine. If any of these happen, you should continue to take your SPIRODISC but do not increase the number of puffs you take. Your chest condition may be getting worse and you could become seriously ill. See your doctor as you may need additional treatment.

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

Instructions for use

- Your doctor, nurse or pharmacist will show you how to use your SPIRODISC inhaler. They will check how you use it from time to time. Not using your SPIRODISC inhaler properly or as prescribed may mean that it will not help your asthma or COPD as it should.

- The SPIRODISC inhaler holds blisters containing salmeterol/fluticasone propionate as a powder.
- There is a counter on top of the device which tells you how many doses are left. It counts down to 0. The numbers 5 to 0 will appear in red to warn you when there are only a few doses left. Once the counter shows 0, your inhaler is empty.

Using your SPIRODISC inhaler

Your inhaler is packaged in a cardboard box and in a protective packaging for safety purposes.

Before using your inhaler, remove it from the protective packaging.

The inhaler will be off when you remove it from the protective packaging.

In an unused inhaler, 60 doses of powder are separately preserved. The dose indicator shows how many doses remain in the inhaler. Each dose is precisely measured and protected according to hygienic conditions. There is no need to refill.

It is easy to use the inhaler. There are three steps:

1. Opening
2. Inhaling
3. Closing

1. Opening

To open your inhaler, press the red button (child lock) to push the outer cover (see Figure 1). When the outer cover is pushed, a small hole is opened in the mouthpiece and a dose of the medicine is ready to be inhaled. When the inhaler is closed, the outer cover rotates

to its initial position and becomes ready for the next use. The outer cover protects the inhaler when not in use.

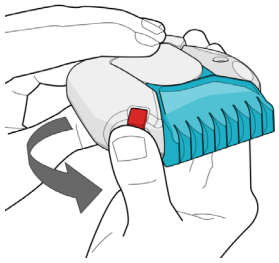


Figure 1

At each opening of the outer lid, one dose is made ready for inhalation. This is seen in the dose indicator. Do not play with the outer lid as this opens blisters and wastes medicine.

2. Inhaling

Hold the inhaler away from your mouth, breathe out as far as is comfortable (Figure 2). Remember: never breathe into the inhaler.

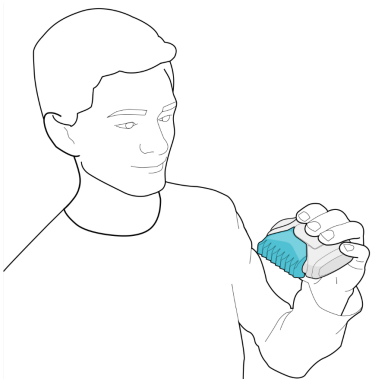


Figure 2

Put the mouthpiece to your lips (see Figure 3). Breathe in long and deeply through the inhaler, not through your nose.

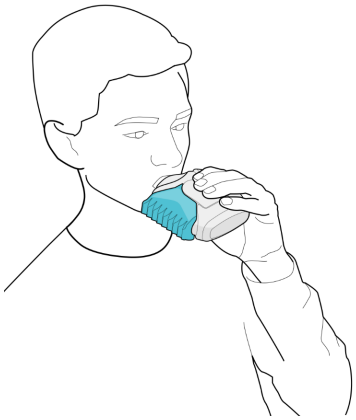


Figure 3

Remove the inhaler from your mouth.

Hold your breath for about 10 seconds, or for as long as is comfortable.

Breathe out slowly.

The inhaler delivers your dose of medicine as a very fine powder. You may or may not taste or feel the powder. **Do not use an extra dose from the inhaler if you do not feel or taste the medicine.**

Afterwards, rinse your mouth with water and spit it out, and/or brush your teeth. This may help to stop you getting thrush and becoming hoarse.

3. Closing

To close the inhaler, you only need to slide the outer lid to its original position. The inhaler is now ready for you to take your next scheduled dose.

As with all inhalers, caregivers should ensure that children prescribed SPIRODISC inhaler use correct inhalation technique, as described above.

If you are advised to take two inhalations, you should repeat steps 1 through 3.

Cleaning your SPIRODISC inhaler

Keep your inhaler dry and clean.

If necessary, you may wipe the mouthpiece of your inhaler with a dry cloth or tissue to clean it.

Keep your inhaler closed when not in use.

Never breathe into the inhaler.

Open the outer cover when you are ready to take the medication.

Do not take more than the prescribed dose.

If you use more SPIRODISC than you should

It is important to use your inhaler as instructed.

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

If you have taken a larger dose than recommended, you may notice your heart beating faster than usual and that you feel shaky. If you have used larger doses for a long period of time, you should talk to your doctor or pharmacist for advice. This is because larger doses of SPIRODISC may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use SPIRODISC

Do not take a double dose to make up for forgotten individual doses. Just take your next dose at the usual time.

If you stop using SPIRODISC

It is very important that you take your SPIRODISC every day as directed. Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of SPIRODISC. This could make your breathing worse. In addition, if you suddenly stop

taking SPIRODISC or reduce your dose of SPIRODISC this may cause you to have problems with your adrenal gland (adrenal insufficiency) which sometimes causes side effects. These side effects may include any of the following:

- stomach pain
- tiredness and loss of appetite, feeling sick
- sickness and diarrhoea
- weight loss
- headache or drowsiness
- low levels of sugar in your blood
- low blood pressure and seizures (fits).

When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, adrenal insufficiency can get worse and you may have any of the side effects listed above.

If you get any side effects, talk to your doctor or pharmacist. To prevent these symptoms occurring, your doctor may prescribe extra corticosteroids in tablet form (such as prednisolone). If you have any further questions on the use of SPIRODISC, ask your doctor, nurse or pharmacist.

4. Possible side effects

SPIRODISC can have side effects.

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

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

- if you notice that your breathing suddenly gets worse immediately after using SPIRODISC. You may be wheezy and cough or be short of breath. Take your fast-acting 'reliever' inhaler immediately
- if you have difficulty breathing and notice itching, a rash (hives) and swelling (usually of the face, lips, tongue or throat), or you may suddenly feel that your heart is beating very fast or you feel faint and light headed (which may lead to collapse or loss of consciousness)

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

Frequent:

- pneumonia (infection of the lung) in COPD patients, or bronchitis. You may notice that you have a fever or chills, increased mucous production, change in mucous colour or increased cough or increased breathing difficulties

Less frequent:

- angina (chest pain)
- glaucoma (increased pressure in the eye)
- changes in the way your heart beats, for example, if you notice an uneven heart beat or your heart gives an extra beat (dysrhythmia). Tell your doctor, but do not stop taking SPIRODISC unless your doctor tells you to.

Frequency not known:

- blurred vision or inability to see

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

Tell your doctor if you notice any of the following:

Frequent:

- headache
- thrush (sore, creamy-yellow, raised patches) in the mouth and throat; sore tongue, hoarse voice or difficulty in speaking and throat irritation. Rinsing your mouth out with water and spitting it out immediately and/or brushing your teeth after taking each dose of your medicine may help. Your doctor may prescribe an anti-fungal medication to treat the thrush.
- aching, swollen joints and muscle pain
- muscle cramps
- bruising and fractures (in COPD patients)
- increased number of colds (in COPD patients)
- inflammation of the sinuses: a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing headache (in COPD patients)

Less frequent:

- noticing you can feel heartbeat (palpitations)
- cataract (cloudy lens in the eye)
- tremor
- fungal infection of the oesophagus, which may make it difficult to swallow
- increases in the amount of sugar (glucose) in your blood (hyperglycaemia). If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetic treatment may be required.
- behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).
- feeling worried or anxious (this effect mainly occurs in children).
- disturbed sleep.
- allergic skin rash

- SPIRODISC may affect the normal production of steroid hormones in the body, particularly if you have taken high doses for long periods of time. The effects include:
  - slowing of growth in children and adolescents
  - thinning of the bones
  - glaucoma
  - weight gain
  - rounded (moon shaped) face (Cushing's Syndrome)

  Your doctor will check you regularly for any of these side effects and make sure you are taking the lowest dose of SPIRODISC to control your asthma or COPD.

Frequency not known:

- depression or aggression (more likely to occur in children)

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: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SPIRODISC.

5. How to store SPIRODISC

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Do not use after the expiry date stated on the 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 SPIRODISC contains

- Each dose contains 50 micrograms of salmeterol (as salmeterol xinafoate) and 100, 250 or 500 micrograms of fluticasone propionate.
- The other ingredient is lactose monohydrate.

What SPIRODISC looks like and contents of the pack

SPIRODISC is a two-toned, circular plastic device containing an aluminium foil strip with 60 regularly placed blisters each containing a white to off-white powder. The device is composed of a white body with a light blue (SPIRODISC 50/100), blue (SPIRODISC 50/250) or dark blue (SPIRODISC 50/500) coloured mouthpiece cap, and a red button. The device is further wrapped in a laminated foil pouch and packed into a cardboard box.

HOLDER OF CERTIFICATE OF REGISTRATION

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This leaflet was last revised in

14 February 2023

REGISTRATION NUMBERS

SPIRODISC 50/100: 55/21.5.4/0278

SPIRODISC 50/250: 55/21.5.4/0279

SPIRODISC 50/500: 55/21.5.4/0280