

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: SEREHALE 50/100µg, 50/250µg, 50/500 µg

Dosage Form & Strength: Accuhaler, Salmeterol 50 mcg and Fluticasone (100 mcg, 250 mcg, 500 mcg)

CTD, Module 1

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

SEREHALE 50/100

SEREHALE 50/250

SEREHALE 50/50

50 microgram /100 microgram /dose inhalation powder, pre-dispensed.

50 microgram /250 microgram /dose inhalation powder, pre-dispensed.

50 microgram /500 microgram /dose inhalation powder, pre-dispensed.

Contains: Sugar (Lactose monohydrate)

SEREHALE 50/100: Fluticasone Blister (1st Blister) contains 12,40 mg of Lactose monohydrate and Salmeterol blister (2nd Blister) contains 12,43 mg of Lactose monohydrate.

SEREHALE 50/250: Fluticasone Blister (1st Blister) contains 12,25 mg of Lactose monohydrate and Salmeterol blister (2nd Blister) contains 12,43 mg of Lactose monohydrate.

SEREHALE 50/500: Fluticasone Blister (1st Blister) contains 12,00 mg of Lactose monohydrate and Salmeterol blister (2nd Blister) contains 12,43 mg of Lactose monohydrate.

Salmeterol/Fluticasone propionate

A diagram of the Accuhaler device is shown on the leaflet in your pack.

Read all this leaflet carefully before you start taking SEREHALE

What is in this leaflet

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

1. What SEREHALE is and what is it used for:

SEREHALE contains two medicines, salmeterol and fluticasone propionate:

- Salmeterol is a long-acting bronchodilator. Bronchodilators help the airways in the 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 this medicine to help prevent breathing problems such as:

- Asthma

- Chronic Obstructive Pulmonary Disease (COPD). **SEREHALE** Accuhaler, at a dose of 50/500 micrograms, reduces the number of flare ups of COPD symptoms.

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

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

Do not take **SEREHALE**:

If you are allergic to salmeterol, fluticasone propionate or to the other ingredient of **SEREHALE** (listed in section 6).

Warnings and precautions

Take special care with **SEREHALE**:

- If you have a heart disease, including an irregular or fast heartbeat
- If you have an overactive thyroid gland
- If you have high blood pressure
- If you have diabetes mellitus (**SEREHALE** may increase your blood sugar)
- If you have low potassium in your blood
- If you have tuberculosis (TB) now or in the past, or other lung infections
- **SEREHALE** may cause blurred visions or visual disturbances.

Children and adolescents:

SEREHALE should not be used in children below 4 years.

Other medicines and SEREHALE:

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

Tell your doctor if you are taking the following medicines, before starting to use

SEREHALE:

- β blockers (such as atenolol, propranolol and sotalol). $\beta\beta$ blockers are mostly used for 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, cobicistat containing products). 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 **SEREHALE**, 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 this medicine affecting your adrenal gland.
- Diuretics, also known as 'water tablets' used to treat high blood pressure.
- Other bronchodilators (such as salbutamol).

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- Xanthine medicines. These are often used to treat asthma.

SEREHALE with food, drink, and alcohol:

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

Pregnancy and breastfeeding and fertility:

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:

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

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

SEREHALE contains:

Sugar (Lactose monohydrate)

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

3. How to take SEREHALE:

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



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

The usual dose is:

For Asthma:

Adults and adolescents aged 12 years and over

- **SEREHALE** Accuhaler 50/100 - One inhalation twice a day
- **SEREHALE** Accuhaler 50/250 - One inhalation twice a day
- **SEREHALE** Accuhaler 50/500 - One inhalation twice a day

Children 4 to 12 years of age

- **SEREHALE** Accuhaler 50/100 - One inhalation twice a day
- **SEREHALE** is not recommended for use in children below 4 years of age.

For adults with Chronic Obstructive Pulmonary Disease (COPD)

- **SEREHALE** Accuhaler 50/500 - One inhalation twice a day

The dose may change to:

- once at night - if you have **night-time** symptoms
- once in the morning - if you have **daytime** symptoms.

It is important to follow your doctor's instructions on how many inhalations to take and how often to take your medicine.

If you are using **SEREHALE** for asthma, your doctor will want to regularly check your symptoms.

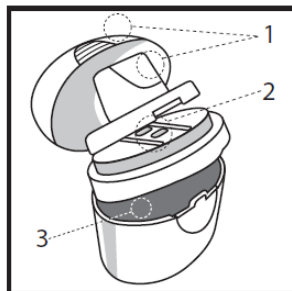
Instructions for use and handling of the SEREHALE

Use of the SEREHALE

DESCRIPTION OF THE SEREHALE

The **SEREHALE** is a device for inhaling at the same time two medicines, in the form of powder, for inhalation in doses. Each medicine is packed separately from the other in one of the two blisters of the specially designed double-blister strips, which are stored in the **SEREHALE**.

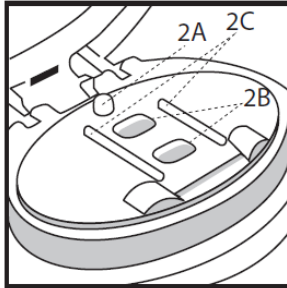
The double-blister strip contains one (1) dose of the medicinal combination.



The **SEREHALE** is comprised of 3 parts:

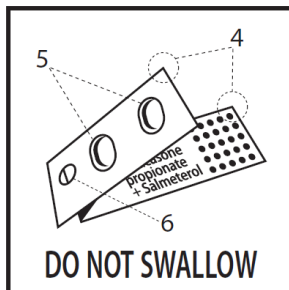
- The mouthpiece and its cap (1).
- The surface (2) on which the double-blister strip is placed (drug supporting surface).
- The storage case (3) which houses the double-blister strips.

The three parts are connected to each other and can be opened separately.



The supporting surface contains:

- An attachment point (2A) where the double-blister strip is attached.
- Two cavities (2B) which accommodate the two blisters of the strip.
- Two strip guides (2C) which firmly secure the double-blister strip in the correct position on the drug supporting surface.

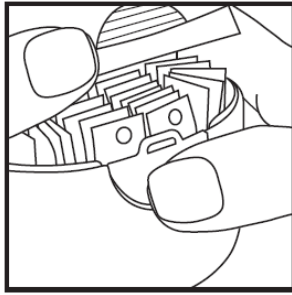


The double-blister strip contains:

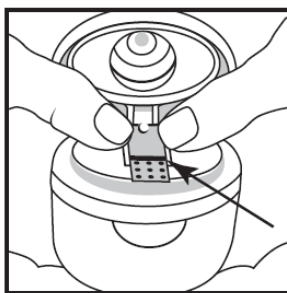
- Two aluminium sheets (4).
- Two blisters (5), one containing fluticasone propionate and the other salmeterol
- A hole (6).

USE OF THE SEREHALE

A. Preparing the device



Open the storage case by pressing as in the figure, take a strip and close the storage case again.



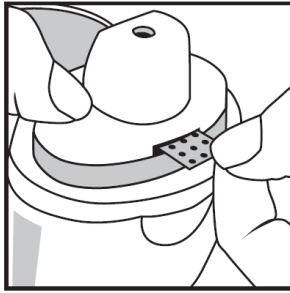
Uncover the mouthpiece completely by applying light pressure on the striped area.

Unlock and push the mouthpiece backwards so as to reveal the drug supporting surface.

Hold the double-blister strip with its shiny surface upwards, so as to see the blue line, as shown by the arrow in the figure. The labeled surface of the strip should face downwards.

Place the hole of the strip on the attachment point of the drug supporting surface. By applying light pressure make sure the strip is securely attached on the attachment point.

The two blisters of the strip will fit in the cavities of the supporting surface and the guides will secure the strip in the correct position.

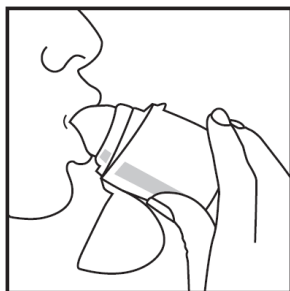


Close the mouthpiece and pull away horizontally the embossed protruding end of the strip to be detached.

The dose is now ready to be inhaled.

B. Inhalation of the dose

Hold the device away from your mouth. Exhale completely. Be careful not to exhale on the mouthpiece of the device. Bring the **SEREHALE** to your mouth and place your lips tightly around the mouthpiece.



Breathe in slowly and deeply from your mouth (and not from your nose) until your lungs are full.

Hold in your breath approximately 5 seconds or as long as you comfortably can and at the same time remove the device from your mouth.

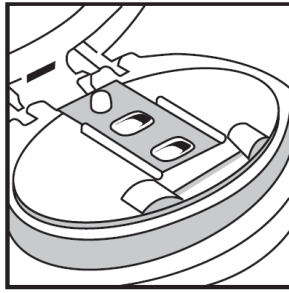
Exhale and continue to breathe normally.

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Open the mouthpiece. You will notice that you have inhaled all the powder and that the blisters of the strip are empty.

Remove the empty strip and proceed to step C.

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

C. Cleaning the device

Following each use, wipe the mouthpiece and the drug supporting surface with a dry cloth or dry paper tissue. Do not use water to clean the device. Close the mouthpiece and its cap.

If you take more SEREHALE than you should:

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

If you forget to take a dose of SEREHALE:

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

If you stop taking SEREHALE

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

4. Possible side effects

SEREHALE can have side effects.

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

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

- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache - this usually gets better as treatment continues.
- Increased number of colds have been reported in patients with COPD.
- Thrush (sore, creamy-yellow, raised patches) in the mouth and throat. Also, sore tongue and hoarse voice 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.

The following side effects have also been reported in patients with Chronic Obstructive Pulmonary Disease (COPD):

- Bruising and fractures.
- Inflammation of sinuses (a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache).
- A reduction in the amount of potassium in the blood (you may get an uneven heartbeat, muscle weakness, cramp).

Less frequent side effects:

- 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.
- Cataract (cloudy lens in the eye).
- Fast heartbeat (tachycardia).
- Feeling shaky (tremor) and fast or uneven heartbeat (palpitations) - these are usually harmless and get less as treatment continues.
- Chest pain.



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- Feeling worried (this effect mainly occurs in children).
 - Disturbed sleep.
 - Allergic skin rash.

Frequency unknown side effects:

- Low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm (hypokalaemia).

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

5. How to store SEREHALE

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

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Store at or below 30 °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 SEREHALE contains:

The active substance in **SEREHALE** is salmeterol (as salmeterol xinafoate) and fluticasone propionate.

Alu-alu strips with two blisters each, containing white powder. One blister contains Fluticasone propionate and lactose monohydrate and the second blister contains Salmeterol xinafoate and lactose monohydrate.

SEREHALE contains: Sugar (Lactose monohydrate).

What SEREHALE looks like and contents of the pack

SEREHALE 50/100, 50/250, 50/500 Accuhaler Powder for Inhalation: A white plastic device, containing 60 alu-alu strips with two blisters each containing white powder, packed into a carton box together.

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Holder of Certificate of Registration

Innovata Pharmaceuticals (Pty) LTD

Crownwood Office Park

100 Northern Parkway

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Johannesburg

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South Africa

This leaflet was revised in

New

Registration number

TBI

Access to the corresponding Professional information.

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