

PATIENT INFORMATION LEAFLET FOR SILEA

SCHEDULING STATUS:

S3

SILEA 0,31 mg/ 3 mL

SILEA 0,63 mg/ 3 mL

SILEA 1,25 mg/ 3 mL

(Inhalation Solution)

Sugar free

Read all of this leaflet carefully because it contains important information for you:

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

1. What SILEA is and what it is used for

SILEA is an inhaled prescription medicine used for the treatment or prevention of asthma in patients 6 years and older.

2. What you need to know before you take SILEA

Do not take SILEA:

- If you are allergic to levalbuterol, racemic albuterol or any of the inactive ingredients of **SILEA**.

Do not give **SILEA** to children under the age of 6 years.

Warnings and precautions:

*Tell your doctor if you are suffering from any of the following medical conditions as treatment with **SILEA** may deteriorate your health:*

- Heart problems
- High blood pressure
- Fits
- Diabetes (condition due to increased sugar level in blood)
- Thyroid problems (increased or decreased function of the thyroid gland)

*If you experience any of the following whilst on treatment with **SILEA**, discontinue treatment and consult your doctor or health care provider immediately:*

- Allergic reactions, may be characterised by rash and itching, swelling in the face, tongue and/or throat.
- Breathing difficulties

- Worsening of your asthma
- Heart-related complications such as chest pain (due to angina pectoris) and irregular heart rates.

Other medicines and SILEA:

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

*Taking **SILEA** together with any of the below medicines may aggravate your health, please tell your doctor if you are taking any of the following:*

- Other medicines for treating asthma.
- Diuretics (water tablets).
- Digoxin (used for treating heart conditions).
- Antidepressants (medicines used to treat depression).

Pregnancy 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 healthcare provider for advice before taking **SILEA**.

Do not take **SILEA** if you are pregnant, planning to have a baby or breastfeeding as safety and efficacy have not been established.

Driving and using machines

SILEA can cause dizziness and fainting, therefore it might impair your ability to drive and operate machinery. Caution is advised until you are fully aware of how **SILEA** affects you.

3. How to take SILEA

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

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

The usual dose is:

- Children 6 to 11 years old: **SILEA** 0,31/ 3 mL three times per day, by nebulisation.
- Adults and children aged 12 years and older: **SILEA** 0,63 mg/ 3 mL three times per day, by nebulisation.

Do not exceed the recommended dose.

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

*If you take more **SILEA** 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 **SILEA**:*

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

4. Possible side effects

SILEA can have side effects.

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

If any of the following happens, stop taking SILEA 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
- Eczema
- Fainting

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

Table 1: Frequent serious side effects in children and adults

Adults and children aged 12 years and older	Children aged 6 to 11 years
Flu-like illness	Flu-like illness
Viral infections, e.g. sore throat, blocked and/or runny nose, coughing (infections are accompanied by fever)	Viral infections, e.g. sore throat, blocked and/or runny nose, coughing (infections are accompanied by fever)
Exacerbation of asthma	Ear infection, indicated by ear pain
Wheezing	Exacerbation of asthma
Swollen nose	Diarrhoea
Irregular or faster heart rhythm	
Chest pain	
High blood pressure (may be indicated by headaches, severe heartbeat and breathing difficulties)	
Low blood pressure (may be indicated by fainting and being pale)	
Diarrhoea	

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

Tell your doctor if you notice any of the following:

Table 2: Other frequent side effects that must be noted and reported to your healthcare provider:

<i>Adults and children aged 12 years and older</i>	<i>Children aged 6 to 11 years</i>
Severe headache	Headache
Dizziness	Extreme tiredness
Tight/inflexible muscle	Fever
Tremors	Pain
Anxiety	Accidental injury
Nervousness	Abdominal pain (stomach pain)
Partial loss of sensitivity in the hand	Muscle pain
A feeling of pins and needles	
Itchy eye	
Dry mouth	
Dry throat	
Bloatedness	
Abdominal pain (stomach pain)	
Nausea	
Vomiting	
Sleeplessness	
Muscle pain	
Leg cramps	

<i>Adults and children aged 12 years and older</i>	<i>Children aged 6 to 11 years</i>
Back pain	
Pain	
Accidental injury	
Sweating	
Chills	

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 **SILEA**.

You may also report any suspected side effects (to Cipla Medpro (Pty) Ltd) by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).

5. How to store SILEA

Store in the original packages at or below 25 °C.

STORE ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

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 SILEA contains

The active substance is Levalbuterol hydrochloride equivalent to Levalbuterol 0,31, 0,63 or 1,25 mg per 3 mL [levalbuterol 0,0103 %, 0,021 % and 0,042 % (w/v)].

The other ingredients are:

- Edetate sodium
- Nitrogen
- Sodium chloride
- Sulphuric acid
- Water for injection

What SILEA looks like and contents of the pack

SILEA is marketed in as a single dose fill form seal (FFS) ampoule made up of low density polyethylene (LDPE) granules containing 3 mL inhalation solution. A strip of 5 ampoules are then overwrapped in triple laminated pouch and then further packed into cardboard cartons containing 5 pouches per carton, corresponding to 25 ampoules per pack.

Instructions on how to use SILEA:

Step 1: Open the foil pouch by tearing the notched edge along the seam of the pouch (**see Figure B**). Remove 1 vial to be used right away. Keep the rest of the unused vials in the foil pouch to protect them from light and heat.

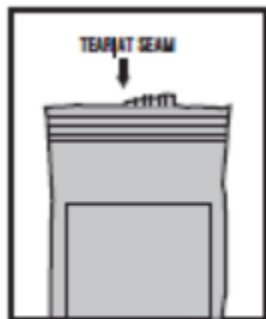


Figure B

Step 2: Hold the vial in your hands. Make sure your thumb and finger cover the twist-off tabs (see **Figure C**).



Figure C

Step 3: While holding the top firmly between your thumb and finger, twist the body of the vial to open the vial (see **Figure C**).

Step 4: Throw away the top of the vial and squeeze the entire contents of the vial into the nebuliser reservoir (see **Figure D**).

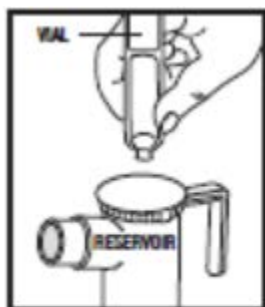


Figure D

Step 5: Connect the nebuliser reservoir to the mouthpiece (see **Figure E.1**) or face mask (see **Figure E.2**).

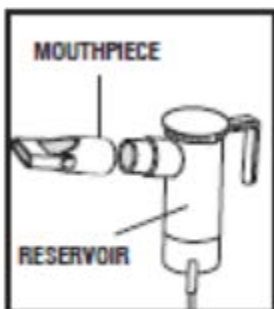


Figure E.1



Figure E.2

Step 6: Connect the nebuliser to the compressor (see **Figure F**).



Figure F

Step 7: Sit in a comfortable, upright position. Place the mouthpiece in your mouth (see **Figure G.1**) or put on your face mask (see **Figure G.2**). Turn on the compressor.



Figure G.1



Figure G.2

Step 8: Breathe as calmly, deeply, and evenly as possible until no more mist is seen in the nebuliser reservoir. Your treatment will take about 5 to 15 minutes. When you do not see any mist in the nebuliser reservoir, your treatment is finished.

Step 9: Clean and store your nebuliser. See the manufacturer's instructions that come with your nebuliser for how to clean and store your nebuliser.

Holder of Certificate of Registration

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04 April 2023

Registration numbers

SILEA 0,31 mg/ 3 mL: 54/10.2.1/0630.627

SILEA 0,63 mg/ 3 mL: 54/10.2.1/0631.628

Cipla Medpro (Pty) Ltd

Levalbuterol 0,31/ 0,63/ 1,25 mg per 3 mL
(Inhalation solution)

SILEA 1,25 mg/ 3 mL: 54/10.2.1/0632.629