

TRIMBOW[®] 100/6/10

TRIMBOW[®] 200/6/10

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using TRIMBOW?

TRIMBOW contains the active ingredients beclometasone dipropionate, formoterol (eformoterol) fumarate dihydrate and glycopyrronium bromide (glycopyrrolate). TRIMBOW is used to prevent symptoms such as shortness of breath, wheezing and cough in adult patients with chronic obstructive pulmonary disease (COPD) and asthma.

For more information, see Section [1. Why am I using TRIMBOW?](#) in the full CMI.

2. What should I know before I use TRIMBOW?

Do not use if you have ever had an allergic reaction to TRIMBOW or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use TRIMBOW?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRIMBOW and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TRIMBOW?

- The recommended dose is two puffs in the morning and two puffs in the evening at the same time every day.
- You should inhale the medicine through your mouth, and this takes the medicine directly into your lungs.

More instructions can be found in Section [4. How do I use TRIMBOW?](#) in the full CMI.

5. What should I know while using TRIMBOW?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using TRIMBOW.• Stop taking TRIMBOW, use your quick-acting “reliever” inhaler and seek medical help immediately if your breathing gets worse, this may include shortness of breath or wheezing (breathing with an audible whistling sound) straight after using TRIMBOW.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not take TRIMBOW to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• TRIMBOW is unlikely to affect your ability to drive and use machines.
Looking after your medicine	<ul style="list-style-type: none">• TRIMBOW 100/6/10 (60, 120 or 180 puff inhalers): store below 30°C for a maximum of 2 months.• TRIMBOW 200/6/10 (60 puff inhaler): store below 30°C for a maximum of 1 month.• TRIMBOW 200/6/10 (120 puff inhaler): store below 30°C for a maximum of 2 months.• From a multipack: store the unused inhaler(s) in a refrigerator (2°C-8°C) until you are ready to use. Do not freeze.

For more information, see Section [5. What should I know while using TRIMBOW?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following very serious side effects happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital. Very serious side effects are: worsening shortness of breath and wheezing, rash, itching, hives on the skin, swelling (of the face, lips, tongue or other parts of the body), eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes (signs of an acute attack of narrow-angle glaucoma), or crushing chest pain often spreading to the arms or neck and sometimes to the shoulders and back (angina).

Tell your doctor as soon as possible if you notice any of the following serious side effects: symptoms of a lung infection such as fever or chills, increased mucus production, change in mucus colour, or increased cough or increased breathing difficulties, severe chills, sore throat, or mouth ulcers.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TRIMBOW[®] 100/6/10

TRIMBOW[®] 200/6/10

Active ingredient(s): beclometasone dipropionate, formoterol (eformoterol) fumarate dihydrate and glycopyrronium bromide (glycopyrrolate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using TRIMBOW. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TRIMBOW.**

Where to find information in this leaflet:

- [1. Why am I using TRIMBOW?](#)
- [2. What should I know before I use TRIMBOW?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TRIMBOW?](#)
- [5. What should I know while using TRIMBOW?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using TRIMBOW?

TRIMBOW contains the active ingredients beclometasone dipropionate, formoterol (eformoterol) fumarate dihydrate, and glycopyrronium bromide (glycopyrrolate).

Beclometasone dipropionate belongs to a group of medicines called corticosteroids which act to reduce the swelling and irritation in your lungs.

Formoterol (eformoterol) fumarate dihydrate and glycopyrronium bromide (glycopyrrolate) are medicines called long-acting bronchodilators. They act in different ways to relax the muscles in your airways, helping to open the airways wider and allowing you to breathe more easily.

TRIMBOW is used to prevent symptoms such as shortness of breath, wheezing and cough in adult patients with chronic obstructive pulmonary disease (COPD) and asthma.

COPD is a serious long-term disease in which the airways become blocked and air sacs inside the lungs become damaged, leading to difficulty in breathing.

Asthma is a serious, long-term disease where the muscles surrounding the airways become tight (bronchoconstriction), and swollen and irritated (inflammation). Symptoms can come and go, which can include shortness of breath, wheezing, chest tightness and cough.

You will use TRIMBOW every day and not only when you have breathing problems or other symptoms of COPD and asthma. This will ensure that it controls your symptoms properly.

2. What should I know before I use TRIMBOW?

Warnings

Do not use TRIMBOW if:

- you are allergic to beclometasone dipropionate, formoterol (eformoterol) fumarate dihydrate, glycopyrronium bromide (glycopyrrolate), or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- do not use this medicine to relieve a sudden attack of breathlessness or wheezing.

Check with your doctor if you:

- have or have had any of the following medical conditions:
 - heart problems (heart pain, pain in the chest, recent heart attack, heart failure, narrowing of the arteries around your heart, disease of your heart valves or any other abnormalities of your heart)
 - heart condition known as hypertrophic obstructive cardiomyopathy (also known as HOCM, a condition where the heart muscle is abnormal)
 - heart rhythm disorders such as irregular heart rate, a fast pulse rate or palpitations or abnormal heart trace (ECG)
 - high blood pressure or swelling and weakening of blood vessels
 - an overactive thyroid gland
 - low blood levels of potassium
 - disease of your liver or kidneys
 - diabetes or high blood sugars
 - a tumour of the adrenal gland
 - tuberculosis (TB)
 - viral or fungal chest infection
 - eye problems called narrow-angle glaucoma
 - prostate problems or difficulty passing urine
 - an infection of the mouth or throat.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You should only use TRIMBOW during pregnancy if you are advised to do so by your doctor. It is preferable to avoid the use of TRIMBOW during labour as it may impact contractions of the uterus.

You should not use TRIMBOW during breastfeeding. You and your doctor will decide whether to discontinue breastfeeding or to discontinue TRIMBOW taking into account the benefit of breastfeeding for your child and the benefit of therapy for you.

Children and adolescents

Do not give this medicine to children and adolescents below the age of 18 years.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with TRIMBOW and affect how it works. These include:

- medicines for HIV such as ritonavir, cobicistat
- medicines for treating high blood pressure, heart conditions and abnormal heart rhythms (such as digoxin, quinidine, disopyramide, procainamide)
- medicines to treat glaucoma
- medicines to treat migraines
- other medicines to treat COPD or asthma (such as theophylline, aminophylline or corticosteroids)
- medicines used to treat allergic reactions (antihistamines)
- medicines to treat depression or mental disorders such as monoamine oxidase inhibitors (phenelzine, isocarboxazid, furazolidone and procarbazine), tricyclic antidepressants (amitriptyline and imipramine), or phenothiazines
- L-dopa, a medicine used to treat Parkinson's Disease
- L-thyroxine, a medicine used to treat an underactive thyroid gland
- oxytocin, used to bring on (induce) labour
- medicines containing alcohol
- fluid or water tablets
- anaesthetics used during surgery
- disulfiram, a medicine used to treat drinking problems
- metronidazole, an antibiotic to treat infection in your body.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TRIMBOW.

4. How do I use TRIMBOW?

How much to use

- The recommended dose is two puffs in the morning and two puffs in the evening at the same time every day.
- Follow the instructions provided and use TRIMBOW until your doctor tells you to stop.
- TRIMBOW is not used for initial therapy. TRIMBOW is used as a maintenance treatment for your COPD or asthma.

How to use the inhaler

TRIMBOW is for inhalation use.

You should inhale the medicine through your mouth, and this takes the medicine directly into your lungs.

This medicine is contained in a pressurised container enclosed in a plastic inhaler with a mouthpiece. Each container provides 60 puffs or 120 puffs or 180 puffs.

If you have been prescribed a container providing 60 puffs or 120 puffs:

There is a counter on the back of the inhaler, which corresponds to the number of puffs left in the container. Each time you press the pressurised container, a puff of medicine is released, and the counter will count down by one. Take care not to drop the inhaler as this may cause the counter to count down.

If you have been prescribed a container providing 180 puffs:

There is an indicator on the back of the inhaler, which tells you how many doses are left. Each time you press the pressurised container, a puff of medicine is released, and the dose indicator rotates by a small amount. The number of puffs remaining is displayed in intervals of 20. Take care not to drop the inhaler as this may cause the dose indicator to count down.

Testing your inhaler

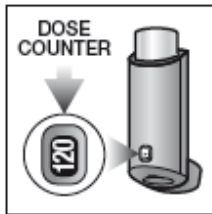
Before using the inhaler for the first time, you should test your inhaler to make sure that it is working properly, as follows.

1. Depending on the inhaler size prescribed for you, check that the dose counter reads 61 or 121 or 180
2. Remove the protective cap from the mouthpiece
3. Hold your inhaler upright with the mouthpiece at the bottom
4. Direct the mouthpiece away from yourself and firmly press the pressurised container to release one puff
5. Check the dose counter. If you are testing your inhaler for the first time, the counter should read:

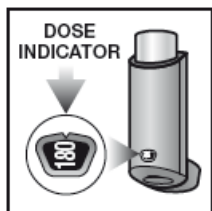
60 - when using the container providing 60 puffs.



120 - when using the container providing 120 puffs



180 - when using the container providing 180 puffs

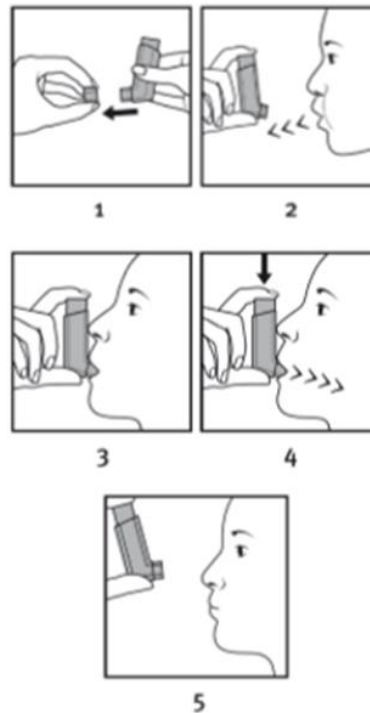


How to use your inhaler

Stand or sit up when inhaling.

IMPORTANT: Do not perform steps 2 to 5 too quickly.

1. Remove the protective cap from the mouthpiece and check that the mouthpiece is clean and free from dust and dirt.
2. Breathe out as slowly and deeply as possible, in order to empty your lungs.
3. Hold the inhaler upright with the mouthpiece at the bottom and place the mouthpiece between your teeth without biting it. Then place your lips around the mouthpiece, with the tongue flat under it.
4. Breathe in slowly and deeply through your mouth to fill your lungs with air (this should take about 4-5 seconds). Just after starting to breathe in, press down firmly on the top of the pressurised container to release one puff.
5. Hold your breath for as long as possible and, finally, remove the inhaler from your mouth and breathe out slowly. Do not breathe out into the inhaler.
6. Check that the dose counter has moved down by one (for 60 and 120 puff inhalers) or that the dose indicator has rotated by a small amount (180 puff inhaler).



For the second puff, keep the inhaler in the upright position for about half a minute, then repeat steps 2 to 5.

If you see 'mist' coming from the top of the inhaler or the sides of your mouth, this means that TRIMBOW will not be getting into your lungs as it should. Take another puff, following the instructions starting again from step 2.

After use

Replace the protective cap.

To prevent a fungal infection in the mouth and throat, rinse your mouth or gargle with water without swallowing it or brush your teeth after each use of your inhaler.

When to get a new inhaler

You should get a replacement when the counter or indicator shows the number 20. Stop using the inhaler when the counter or indicator shows 0, as any medicine left in the inhaler may not be enough to give you a full puff.

If you have a weak grip, it may be easier to hold the inhaler with both hands. Hold the upper part of the inhaler with both index fingers and its lower part with both thumbs.

If you find it difficult to use the inhaler while starting to breathe in, you may use a suitable spacer device. Ask your doctor or pharmacist about this device.

It is important that you read the package leaflet which is supplied with your spacer device and that you carefully follow the instructions on how to use the spacer device and how to clean it.

Cleaning the TRIMBOW inhaler

You should clean your inhaler once a week.

1. Do not remove the pressurised container from the inhaler and do not use water or other liquids to clean your inhaler.

2. Remove the protective cap from the mouthpiece by pulling it away from your inhaler.
3. Wipe inside and outside of the mouthpiece and the inhaler with a clean, dry cloth or tissue.
4. Replace the mouthpiece cap.

When to use TRIMBOW

You should use TRIMBOW every day, even when your COPD or asthma is not troubling you.

If you feel that the medicine is not working or you are getting breathless or wheezy, talk to your doctor. **Do not use this medicine to relieve or treat a sudden attack of breathlessness or wheezing.**

How long to use TRIMBOW

Continue using TRIMBOW for as long as your doctor tells you.

Do not stop using TRIMBOW or lower the dose, even if you are feeling better or have no symptoms.

It is important to use TRIMBOW every day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you forget to use TRIMBOW

TRIMBOW should be used regularly at the same time each day. If you miss your dose at the usual time, use it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much TRIMBOW

If you think that you have used too much TRIMBOW, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TRIMBOW?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TRIMBOW.

Contact your doctor if you experience blurred vision or other visual disturbances.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if:

- you become pregnant while taking this medicine
- your breathing gets worse, this may include shortness of breath or wheezing (breathing with an audible whistling sound) straight after using TRIMBOW. Stop taking TRIMBOW use your quick-acting "reliever" inhaler.

Remind any doctor, dentist, or pharmacist you visit that you are using TRIMBOW.

Things you should not do

- Do not stop taking your medicine or lower the dosage without checking with your doctor.
- Do not take TRIMBOW to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

TRIMBOW contains ethanol.

TRIMBOW contains 8.856 mg of ethanol absolute (alcohol) in each actuation, which is equivalent to 17.712 mg per dose of two actuations. The amount in two actuations of this medicine is equivalent to less than 1 mL of wine or beer. The small amount of alcohol in this medicine will not have any noticeable effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TRIMBOW affects you.

TRIMBOW is unlikely to affect your ability to drive and use machines.

Looking after your medicine

Do not expose to temperatures higher than 50°C.

Do not pierce the pressurised container.

TRIMBOW 100/6/10

60, 120 or 180 puff inhalers:

Store below 30°C for a maximum of 2 months. Your pharmacist will enter the dispensing date on a label affixed to the inhaler.

From a multipack:

Store the unused inhaler(s) in a refrigerator (2°C-8°C) until you are ready to use. Do not freeze.

Before use, take one inhaler out of the refrigerator for some minutes to allow for the solution to warm up. After first use, store the inhaler below 30°C for a maximum of 2 months. Enter the date of first use on the removable label and affix to the inhaler. **Do not put the inhaler back into the refrigerator.**

TRIMBOW 200/6/10

60 puff inhaler:

Store the inhaler below 30°C for a maximum of 1 month. Your pharmacist will enter the dispensing date on a label affixed to the inhaler.

120 puff inhaler:

Store the inhaler below 30°C for a maximum of 2 months. Your pharmacist will enter the dispensing date on a label affixed to the inhaler.

From a multipack:

Store the unused inhaler(s) in a refrigerator (2°C-8°C) until you are ready to use. Do not freeze.

Before use, take one inhaler out of the refrigerator for some minutes to allow for the solution to warm up. After first use, store the inhaler below 30°C for a maximum of 2 months. Enter the date of first use on the removable label and affix to the inhaler. **Do not put the inhaler back into the refrigerator.**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Infections and infestations: <ul style="list-style-type: none">• sore, raised patches in the mouth, throat or oesophagus (food pipe) caused by a fungal infection (oral thrush). Rinsing your mouth out with water immediately after using the inhaler may prevent this side effect	Speak to your doctor if you have any of these less serious side effects and they worry you.

- dry mouth, sore mouth, burning sensation of the lips, tooth decay
- sore, dry or irritated throat, swallowing difficulties
- flu-like symptoms
- runny or stuffy nose and sneezing, nose bleeds
- feeling of tension or fullness in your sinuses
- fungal infection of the vagina with itching, burning and white discharge (thrush)

Respiratory disorders:

- hoarseness of the voice
- cough

Nervous system disorders:

- abnormal or reduced sense of taste
- headache

Ear and labyrinth disorders:

- inflammation of the ear

Skin disorders:

- skin rash, hives, itchy skin
- bleeding or bruising more easily than normal, bleeding into the tissues
- increased sweating, flushing of skin

Renal and urinary disorders:

- painful, difficult or frequent urination (may be a sign of a urinary tract infection or problems)

Gastrointestinal disorders:

- diarrhoea, feeling sick, upset stomach, stomach discomfort after meals

Metabolism and nutrition disorders:

- decreased appetite

Musculoskeletal and connective tissue disorders:

- muscle cramps or pain, pain in arms, legs or chest muscles

General disorders and administration site conditions:

- swelling of the hands and feet
- dizziness, fatigue, sleep disorders

<p>Neurological disorders:</p> <ul style="list-style-type: none"> restlessness, trembling, numbness, weakness <p>Cardiac disorders:</p> <ul style="list-style-type: none"> irregular heartbeat, sensation of fast, slow or missed heart beats, palpitations <p>Immune system disorders:</p> <ul style="list-style-type: none"> sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body <p>Eye disorders:</p> <ul style="list-style-type: none"> eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes (signs of an acute attack of narrow-angle glaucoma) 	
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<p>Endocrine disorders</p> <ul style="list-style-type: none"> problems with how your adrenal glands work <p>Musculoskeletal and connective tissue disorders</p> <ul style="list-style-type: none"> thinning of your bones growth retardation (children and adolescents) <p>Eye disorders</p> <ul style="list-style-type: none"> clouding of the lens of your eyes (cataracts) <p>Psychiatric disorders</p> <ul style="list-style-type: none"> depression, mental disorders, feeling worried, nervous, over-excited or irritable changes in behaviour (children and adolescents). 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Serious side effects

Serious side effects	What to do
<p>Respiratory disorders:</p> <ul style="list-style-type: none"> symptoms of a lung infection such as fever or chills, increased mucus production, change in mucus colour, or increased cough or increased breathing difficulties worsening shortness of breath and wheezing immediately after using TRIMBOW <p>Infections and Infestations:</p> <ul style="list-style-type: none"> severe chills, sore throat or mouth ulcers <p>Cardiac disorders:</p> <ul style="list-style-type: none"> crushing chest pain often spreading to the arms or neck and sometimes to the shoulders and back (angina) <p>Investigations*</p> <ul style="list-style-type: none"> changes in blood pressure changes in blood levels of sugars, electrolytes, hormones, blood cells, cells to help your blood clot, fatty acids, ketones or proteins in the blood <p>*These tests will be requested and interpreted by your doctor from time to time to check your progress.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TRIMBOW contains

<p>Active ingredients (main ingredient)</p>	<ul style="list-style-type: none"> beclometasone dipropionate formoterol (eformoterol) fumarate dihydrate glycopyrronium bromide (glycopyrrolate).
<p>Other ingredients (inactive ingredients)</p>	<ul style="list-style-type: none"> dilute hydrochloric acid ethanol absolute norflurane

Do not take this medicine if you are allergic to any of these ingredients.

What TRIMBOW looks like

TRIMBOW is a pressurised inhalation solution.

TRIMBOW comes in a pressurised container (coated aluminium), with a metering valve. The pressurised container is inserted in a grey plastic inhaler. This incorporates a mouthpiece provided with a plastic protective red cap (TRIMBOW 100/6/10) or green cap (TRIMBOW 200/6/10) and a dose counter.

TRIMBOW 100/6/10

Pack of 1 container with either 60, 120 or 180 puffs.

Multipack containing 240 puffs (2 containers of 120 puffs each).

Multipack containing 360 puffs (3 containers of 120 actuations each).

Not all pack sizes may be marketed.

TRIMBOW 200/6/10

Pack of 1 container with either 60 or 120 puffs.

Multipack containing 240 puffs (2 containers of 120 puffs each).

Multipack containing 360 puffs (3 containers of 120 puffs each).

Not all pack sizes may be marketed

TRIMBOW 100/6/10 (AUST R 314166)

TRIMBOW 200/6/10 (AUST R 368010)

Who distributes TRIMBOW

Chiesi Australia Pty Ltd
Suite 3, 22 Gillman Street,
Hawthorn East, VIC 3123
Australia

E: medicalaffairs.au@chiesi.com

W: www.chiesi.com.au

This leaflet was prepared in June 2022.