
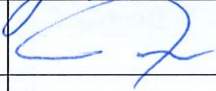



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<b>BRONCHITOL INSTRUCTION LEAFLET AUSTRALIA</b>			

	Name	Position	Signature	Date
Author:	J. Liberatore	QA Officer		17 Jan 23
Reviewed by:	J. Makasiar	Senior QA Officer		17 Jan 23
Authorised by:	A. Dooley	QA Manager		23 Jan 23

## 1.0 MATERIAL IDENTIFICATION

- 1.1 Standard Name Bronchitol Instruction Leaflet Australia
- 1.2 Alternate Name Bronchitol Instruction Leaflet AU
- 1.3 Description Material Marusumi UWF White Bank white 68µm, 52.3gsm.  
Folded leaflet.
- 1.4 Packaging The packaging must be adequate to prevent contamination of the leaflets.
- 1.5 Dimensions 105mm x 28.17mm +1.5mm (folded size)  
105mm x 225.425mm ±1.0mm (unfolded size)

## 2.0 ARTWORK

As per attached artwork.

- 2.1 Artwork Number CSP471/03

## 3.0 APPROVED SUPPLIER

CCL Label.

## 4.0 STORAGE CONDITIONS

Store in clean, dry place.

## 5.0 DIMENSIONS AND PRINT

Inspect the leaflets for the attributes listed on FM-140 release of packaging materials – leaflets.

## 6.0 INSPECTION AND SAMPLING

Inspect and sample according to FM-140 release of packaging materials – leaflets. Inspect as per SOP-173.

## 7.0 ACCEPTANCE LIMITS

Acceptance limits are listed on FM-140 release of packaging materials – leaflets. Inspect as per SOP-173.

## 8.0 SHELF LIFE

Five years as per the manufacturer's Certificate of Conformance.

**BRONCHITOL INSTRUCTION LEAFLET AUSTRALIA****9.0 SAMPLE – N/A****10.0 DOCUMENT CHANGE HISTORY**

Version	Date Effective	Section	Description and Rationale
08	27Jan23	<b>1.3</b>	Update to material type name as per OPS-22-044
		<b>3.0</b>	Update Supplier to CCL as per OPS-22-044.
		<b>8.0</b>	Changed wording for expiry to state as per C of C as CCL states expiry on the C of C.
07	19Dec22	<b>2.1, Artwork</b>	Artwork version updates, as per OPS-21-019.
06	02Jul19	<b>All</b>	Updated to latest template version as per SOP-021.
05	15May17	<b>All</b>	Updated to latest template version as per SOP-021.
		<b>1.3</b>	Corrected material description weight to 55.3±3gsm.
		<b>3.0</b>	Updated name to GPIAC Ltd. as per CR#686.
04	25-May-15	<b>1.5</b>	Tolerance for dimensions were added, as per CAR#604.
03	24-May-13	<b>All</b>	Document update to current version of template TE-014-04 as per SOP-021 and CR498.
		<b>2.1</b>	Artwork number update to “CSP471/02”.
		<b>Artwork</b>	Change manufacturer address to “20 Rodborough road, Frenchs Forest NSW 2086 Australia” as per CR463.
			Update artwork number to “CSP471/02”.
02	05-Sept-11	<b>1.3</b>	Material change from “Silver White Bank 64µm ± 2µm” to “Interplus Bank White 52.3gsm” as per CR363.
01	09-Feb-11	<b>All</b>	New Document.

END OF DOCUMENT



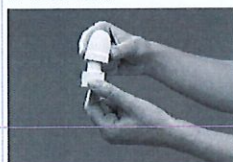
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## Inhalation Device Instruction Leaflet

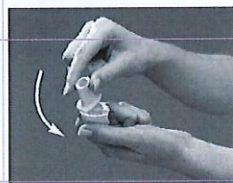
The following steps explain how to use the inhaler.  
There is some more advice on how to look after your inhaler after these steps.

### 1. Take off the cap



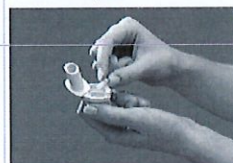
- Using both hands, hold the inhaler upright and take off the cap.

### 2. Open the Inhaler



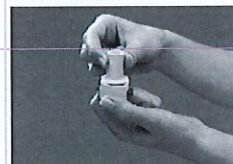
- Hold the bottom of the inhaler firmly with one hand.
- Then open it by turning the mouth-piece in the direction of the arrow on the inhaler.

### 3. Put in the capsule



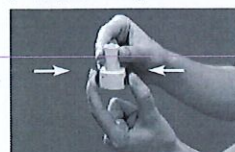
- First make sure your hands are dry.
- Then take out a capsule from the blister (only remove the capsule just before use).
- Put the capsule into the capsule-shaped space in the bottom of the inhaler.

### 4. Close the Inhaler



- Keep the inhaler in an upright position.
- Then twist the mouth-piece into the closed position - when it is closed you will hear a 'click'.

### 5. Make a hole in the capsule



- This lets the powder in the capsule be released when you breathe in. In this leaflet we call making the hole 'piercing'.
- Hold the inhaler upright and fully press in both 'Piercing' buttons on the sides of the inhaler at the same time, then release them. Only do this once. This is because piercing the capsule more than once may make it split or break-up.

### 6. Prepare for Inhalation



- Tilt the inhaler so that the mouth-piece faces slightly downward.
- Do this until the capsule drops forward into the spinning chamber.
- Keep the inhaler tilted in this way and breathe out completely (away from the inhaler).

### 7. Inhale

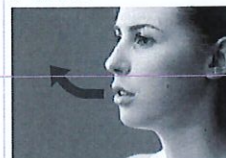


- Tilt your head back slightly.
- Keeping the inhaler tilted downward, put the inhaler to your mouth and make sure you close your lips tightly around the mouth-piece.

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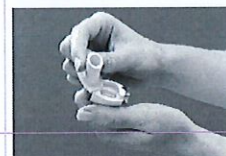
- Take a steady deep breath in, to fill your lungs - then hold your breath for 5 seconds. When you breathe in you should hear a 'rattling' sound as the capsule spins in the inhaler. If this does not happen, the capsule may be stuck.
- If you do not hear the rattling, hold the inhaler mouth-piece down, and tap the bottom firmly. Do not try to loosen the capsule by pressing the piercing buttons again. Repeat the inhalation to get your dose.

### 8. Breathe out



- Take the inhaler away from your mouth.
- Breathe out, and then breath normally again.

### 9. Check the capsule



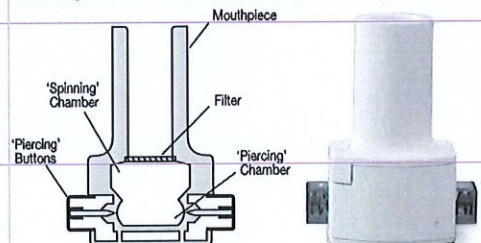
- Look to see if the capsule is empty - the capsule must spin in the inhaler in order to empty. If the capsule has not emptied you may need to repeat steps 6 to 8.

### 10. Take out the used capsule and throw it away.

- 11. Repeat the Steps 3 to 10 for each capsule until all ten are used. To get the best results from Bronchitol, inhale each capsule one after another.

### Inhaler Device Diagram

Below is a diagram that shows what the inhaler looks like. Only use the inhalers provided in the pack.



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### Extra Information on how to look after your inhaler

- Keep your inhaler dry and always make sure your hands are dry before using it.
- Never breathe or cough into your inhaler.
- Never take your inhaler apart.
- Never place a capsule directly into the mouth-piece of your inhaler.
- Never leave a used capsule in your inhaler chamber.
- Use a new inhaler each week.
- If your inhaler breaks, use your second inhaler and talk to your doctor.
- Cleaning the Inhaler - Usually your inhaler will give you the correct dose of medicine for 7 days without needing cleaning. However, if your inhaler does need cleaning, the steps to follow are:

1. Wash your inhaler in warm water with the mouth-piece open.
2. Shake it until there are no large water droplets left in the inhaler.
3. Leave it to dry in the air - lay it on its side with the mouth-piece open.
4. You must let it fully dry, this can take up to 24 hours. While it is drying, use your other inhaler.

Distributed by: BTC Speciality Health  
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Vic 3122 Australia.  
[www.btchealth.com.au](http://www.btchealth.com.au)  
Ph. 1800 100 282

BTC Speciality Health.

**pharmaxis**

Manufactured by: Pharmaxis Ltd  
20 Rodborough Road  
Frenchs Forest  
NSW 2086

AUST R 168002



SCALE: 100%

BPN: 113924

PL 14124

CLIENT DESCRIPTION CODE	Pharmaxis Ltd. BRONCHITOL INSTRUCTION LEAFLET AUSTRALIA CSP471/03	COLOUR/S BLACK	Department	Signature	Date	Comments
SIZE Unfolded:	105x225.425mm	DIE LINE	REG	<i>[Signature]</i>	10 OCT 2022	Approved.
Folded:	105x28.17mm	(NOTE: DOES NOT PRINT)	QA	<i>[Signature]</i>	11 OCT 22	N/A
DATE	06/10/21			<i>[Signature]</i>	11 OCT 22	

### History of Changes:

06/10/21 7.00am Update as per supplied pdf, upgrade to hires images, code to CSP471/03. re Jonas

**brandpack**  
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ONLY