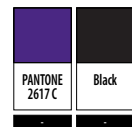


Project Name / Design	UK IE Calpol FromBirth SalineSpray 15ml Leaflet		
Date	30.07.2020	Country / Market(s) - Languages	Ireland, United Kingdom
Job / Version Number	401872393_r6	Technical Spec. / Drawing #	St 695 ZT 695-1
Component Type	Brochure/Leaflet/Insert	Dimensions	148 x 210 mm
New Component / Item Code	11506546-00	Manufacturing / Packaging Fill Site	EM-FamarMadrid_Alcorcon_Spain
Old Component / Item Code	11504909-04	Printer Name	N/A
Pharma Code / Laetus Code	672	Print Method	N/A
Product / Eurocode / Mat. ID Code	9216402	Substrate	N/A
ArtWorks ID:	EMEA_2019_00009192_000	PC spec	N/A

ARTWORK SPECIFICS



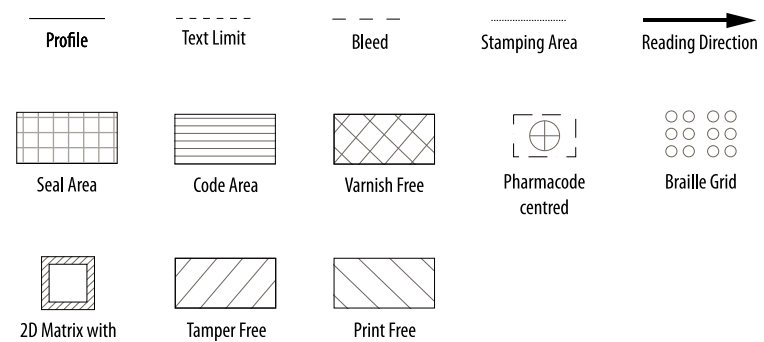
REPRESENTATION: Colours represented with a diagonal line have been modified to aid PDF approval.

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TECHNICAL DETAILS



FONTS

Body Copy Size 8.5pt



1 What CALPOL® Saline Nasal Spray is for

CALPOL® Saline Nasal Spray is suitable for infants, babies, children, pregnant women and adults.

CALPOL® Saline Nasal Spray is a preservative-free isotonic saline solution used for treating blocked, dry or irritated nasal passages caused by cold and flu, sinusitis, allergy including hay fever and post-nasal surgery. It works by rinsing and restoring moisture to the nasal passages/mucosa.

COLD AND FLU

When suffering from cold and flu your nasal lining becomes irritated which leads to production of more mucus than normal resulting in a runny and blocked nose. CALPOL® Saline Nasal Spray helps reduce nasal congestion by thinning the mucus and rinsing it away.

CALPOL® Saline Nasal Spray can aid with feeding and sleeping for infants and babies suffering from cold and flu as it acts to gently wash away the mucus that causes the blocked nose allowing your child to breathe more easily.

SINUSITIS

CALPOL® Saline Nasal Spray provides temporary relief of nasal congestion associated with sinusitis by effectively thinning and flushing away the mucus that causes the blocked nose.

ALLERGY including HAY FEVER

CALPOL® Saline Nasal Spray when regularly used will assist in washing away irritants that trigger allergies e.g. hay fever. By cleaning the nasal tissue, it washes away the irritants and so helps to minimise the symptoms associated with allergy, such as a runny or blocked nose and restore the normal cleaning function of the mucus membranes of the nose.

POST-NASAL SURGERY

CALPOL® Saline Nasal Spray will help remove dry blood and mucus crusts following nasal surgery.

2 How to use CALPOL® Saline Nasal Spray

Follow the instructions below to ensure that you use CALPOL® Saline Nasal Spray correctly:

- For nasal use only.

Warnings

- Keep out of the sight and reach of children.
- Do not use CALPOL® Saline Nasal Spray if you have known hypersensitivity to sodium chloride or to any of the other ingredients.

- One bottle should be used only by the same person as the use of this dispenser by more than one person may spread infection.
- If symptoms persist after 14 days, or worsen, or if new symptoms occur, stop use and consult a healthcare professional.

In the case of any serious incident that occurs with this product, please report this to the manufacturer and to your government's health authority.

You can also report side-effects directly via the Yellow Card Scheme at:

<http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side-effects you can help provide more information on the safety of this medical device.

First Use

- Do not use if the packaging is damaged before opening.
- Remove the protective cap.
- To make sure your pump is working, test spray into the air before you use it for the first time and whenever you have not used it for a week or more.
- Hold the bottle away from you and press down until you can see a fine mist.

Infants and babies up to 2 years

- Lay your child down and turn their head to one side.
- Insert nozzle into nostril and press the spray head once.
- Remove nozzle from the nostril and return the bottle to vertical position, pump once to refill the pump mechanism.
- Repeat the application in the other nostril.

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turn over ▶

Children over 2 years and adults

- Insert the nozzle into the nostril. Keep the bottle vertical.
- Spray deep into the nostril by pressing the spray head once. It is recommended to breathe in through this nostril while holding the other closed.
- Repeat the application in the other nostril.

Check the table below to see how much to use.

Infants and babies up to 2 years	One spray into each nostril as often as required
Children over 2 years and adults	One to two sprays into each nostril as often as required

After using your nasal spray

Wipe the nozzle with a clean tissue and put the protective cap back on.

3 Storing CALPOL® Saline Nasal Spray

Store below 25°C. Keep out of the sight and reach of children. Do not use after the date shown as an expiry date on the packaging. The expiry date refers to the last day of the month. Note the date of first opening on the container. Discard 12 weeks after first opening.

4 Further Information

What's in CALPOL® Saline Nasal Spray?

INGREDIENTS: Aqua, sodium chloride (0.8%), calcium chloride, potassium chloride, magnesium chloride, sodium bicarbonate. [PR-016807].

Each bottle contains approximately 100 sprays.

15ml



Johnson & Johnson GmbH, Johnson & Johnson Platz 2, D-41470 Neuss, Germany.

Distributors:

Johnson & Johnson Ltd., High Wycombe, HP12 4EG, UK.

Johnson & Johnson (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

CALPOL® is a registered trade mark.

Symbol definitions:

Manufacturer:

Batch code:

Use-by date:

Sterilised using aseptic processing techniques:

Medical device:

Revision Date: Version 1, June 2020 UK/IE.

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