1. NAME OF THE MEDICINAL PRODUCT:

Ipravent Respules

(Ipratropium Nebuliser Solution BP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:
Each 2 ml contains:
Ipratropium Bromide (Monohydrate) BP 522 mcg
Equivalent to Ipratropium Bromide (Anhydrous) 500 mcg
In an Isotonic solution..q.s

3. PHARMACEUTICAL FORM:
Nebuliser solution

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:
Ipravent Respules is indicated for treatment of reversible bronchospasm associated with chronic obstructive pulmonary disease (COPD).

Ipravent Respules is indicated, when used concomitantly with inhaled beta$_2$-agonists, for treatment of reversible airways obstruction as in acute and chronic asthma.

4.2 Posology and method of administration:
The dosage should be adapted to the individual needs of the patient. In children aged 12 years and under, only ipratropium bromide respirator solution 1 ml should be used.

The following doses are recommended:

Adults (including the elderly) and children over 12 years of age:
250 - 500 micrograms 3 to 4 times daily 3 to 4 times daily.

For treatment of acute bronchospasm, 500 micrograms.

Repeated doses can be administered until the patient is stable. The time interval between the doses may be determined by the physician.

It is advisable not to exceed the recommended daily dose during either acute or maintenance treatment. Daily doses exceeding 2 mg in adults and children over 12 years of age should only be given under medical supervision.

Children 6 - 12 years of age:
250 micrograms up to a total daily dose of 1mg.
The time interval between doses may be determined by the physician.

Children 0 – 5 years of age (for treatment of acute asthma only):
125 – 250 micrograms up to a total daily dose of 1 mg.

Ipratropium bromide should be administered no more frequently than 6 hourly in children under 5 years of age.

For acute bronchospasm, repeated doses may be administered until the patient is stable.

If therapy does not produce a significant improvement or if the patient's condition gets worse, medical advice must be sought. In the case of acute or rapidly worsening dyspnoea (difficulty in breathing) a doctor should be consulted immediately.

Ipravent Respules may be combined with a short-acting beta$_2$-agonist in the same nebuliser chamber, for simultaneous administration where co-administration is required. The solution should be used as soon as possible after mixing and any unused solution should be discarded.

Ipravent Respules can be administered using a range of commercially available nebulising devices. The dose of nebuliser solution may need to be diluted in order to obtain a final volume suitable for the particular nebuliser being used (usually 2 – 4 ml); if dilution is necessary use only sterile sodium chloride 0.9% solution.

Ipravent Respules and disodium cromoglycate inhalation solutions that contain the preservative benzalkonium chloride should not be administered simultaneously in the same nebuliser as precipitation may occur.

The unit dose vials are intended only for inhalation with suitable nebulising devices and should not be taken orally or administered parenterally.

Please refer to the patient information leaflet for instructions on use with a nebuliser.

4.3 Contraindications:
Known hypersensitivity to atropine or its derivatives, or to any other component of the product.

4.4 Special warnings and precautions for use:
Use of the nebuliser solution should be subject to close medical supervision during initial dosing.

Immediate hypersensitivity reactions following the use of Ipratropium Nebulizer Solution have been demonstrated by cases of urticaria, angioedema, rash, bronchospasm, oropharyngeal oedema and anaphylaxis.

Caution is advocated in the use of anticholinergic agents in patients predisposed to or with narrow-angle glaucoma, or with pre-existing urinary outflow tract obstruction (e.g. prostatic hyperplasia or bladder-outflow obstruction).

As patients with cystic fibrosis may be prone to gastro-intestinal motility disturbances, Ipratropium Nebulizer Solution, as with other anticholinergics, should be used with caution in these patients.

There have been isolated reports of ocular complications (i.e. mydriasis, increased intra-ocular pressure, narrow-angle glaucoma, eye pain) when aerosolised ipratropium bromide, either alone or in combination with an adrenergic beta$_2$-agonist, has come into contact with the eyes during nebuliser therapy.

Eye pain or discomfort, blurred vision, visual halos or coloured images in association with red eyes from conjunctival congestion and corneal oedema may be signs of acute narrow-angle glaucoma. Should any combination of these symptoms develop, treatment with miotic drops should be initiated and specialist advice sought immediately.
Patients must be instructed in the correct administration of Ipratropium Nebulizer Solution. Care must be taken not to allow the solution or mist to enter the eyes. It is recommended that the nebulised solution is administered via a mouthpiece. If this is not available and a nebuliser mask is used, it must fit properly. Patients who may be predisposed to glaucoma should be warned specifically to protect their eyes.

As with other inhalation therapy, inhalation induced bronchoconstriction may occur with an immediate increase in wheezing after dosing. This should be treated straight away with a fast acting inhaled bronchodilator. Ipratropium Nebulizer Solution should be discontinued immediately, the patient assessed and, if necessary, alternative treatment instituted.

4.5 Interaction with other medicinal products and other forms of interaction:
There is evidence that the administration of Ipratropium Nebulizer Solution with beta-adrenergic drugs and xanthine preparations may produce an additive bronchodilatory effect.

The risk of acute glaucoma in patients with a history of narrow-angle glaucoma (see Special Warnings and Precautions for Use) may be increased when nebulised ipratropium bromide and beta$_2$-agonists are administered simultaneously.

4.6 Fertility, Pregnancy and lactation:
The safety of Ipratropium Nebulizer Solution during human pregnancy has not been established. The benefits of using Ipratropium Nebulizer Solution during a confirmed or suspected pregnancy must be weighed against the possible hazards to the unborn child. Preclinical studies have shown no embryotoxic or teratogenic effects following inhalation or intranasal application at doses considerably higher than those recommended in man.
It is not known whether ipratropium bromide is excreted into breast milk. It is unlikely that ipratropium bromide would reach the infant to an important extent, however caution should be exercised when Ipratropium Nebulizer Solution is administered to nursing mothers.

Preclinical studies performed with ipratropium bromide showed no adverse effect on fertility (see section 5.3). Clinical data on fertility are not available for ipratropium bromide.

4.7 Effects on ability to drive and use machines
No studies on the effects on the ability to drive and use machines have been performed. However, patients should be advised that they may experience undesirable effects such as dizziness, accommodation disorder, mydriasis and blurred vision during treatment with Ipratropium Nebulizer Solution. If patients experience the above mentioned side effects they should avoid potentially hazardous tasks such as driving or operating machinery.

4.8 Undesirable effects:
Many of the listed undesirable effects can be assigned to the anticholinergic properties of Ipratropium Nebulizer Solution. As with all inhalation therapy Ipratropium Nebulizer Solution may show symptoms of local irritation. Adverse drug reactions were identified from data obtained in clinical trials and pharmacovigilance during post approval use of the drug.

The most frequent side effects reported in clinical trials were headache, throat irritation, cough, dry mouth, gastro-intestinal motility disorders (including constipation, diarrhoea and vomiting), nausea, and dizziness.

Frequencies

Very common	≥ 1/10
Common	≥ 1/100 < 1/10
Uncommon	≥ 1/1,000< 1/100
Rare	≥ 1/10,000 < 1/1,000
Very rare	< 1/10,000

Immune system disorder	
Hypersensitivity	Uncommon
Anaphylactic reaction	Uncommon
Angioedema of tongue, lips & face	Uncommon
Nervous system disorders	
Headache	Common
Dizziness	Common
Eye disorders	
Blurred vision	Uncommon
Mydriasis (1)	Uncommon
Intraocular pressure increased (1)	Uncommon
Glaucoma (1)	Uncommon
Eye pain (1)	Uncommon
Halo vision	Uncommon
Conjunctival hyperaemia	Uncommon
Corneal oedema	Uncommon
Accommodation disorder	Rare
Cardiac Disorders	
Palpitations	Uncommon
Supraventricular tachycardia	Uncommon
Atrial fibrillation	Rare
Heart rate increased	Rare
Respiratory, Thoracic and Mediastinal Disorders	
Throat irritation	Common
Cough	Common
Bronchospasm	Uncommon

Patient Information Leaflet

Ipravent Respules

(Ipratropium Nebulizer Solution BP 500 mcg/ 2 ml)

Information for the user

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Ipravent Respules are and what they are used for
The name of your medicine is Ipravent Respules (called Ipratropium Nebulizer Solution in the rest or in this leaflet). This changes your medicine into a mist for you to breathe in.
Ipratropium Nebulizer Solution contains a medicine called ipratropium bromide. This belongs to a group of medicines called bronchodilators. It is used to make breathing easier for people who have breathing difficulties, such as in chronic asthma or chronic obstructive pulmonary disease (COPD).
Ipratropium Nebulizer Solution can be taken at the same time as medicines called 'beta$_2$-agonist bronchodilators' such as salbutamol.
Ipratropium Nebulizer Solution works by opening up your airways.

2. Before you use Ipravent Respules
Do not use Ipratropium Nebulizer Solution if:
- You are allergic (hypersensitive) to ipratropium bromide or any of the other ingredients in Ipratropium Nebulizer Solution (listed in Section 6 below)
- You are allergic (hypersensitive) to medicines that are similar to Ipratropium Nebulizer Solution, such as atropine

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Ipratropium Nebulizer Solution.

Take special care with Ipratropium Nebulizer Solution
Check with your doctor or pharmacist before using your medicine if:
- You have cystic fibrosis
- You have glaucoma or have been told that you may develop it
- You are a man who has prostate problems
- You have problems passing water (urine)
- You are pregnant, likely to get pregnant or if you are breast-feeding

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Ipratropium Nebulizer Solution.

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines.
This is because Ipratropium Nebulizer Solution can affect the way some other medicines work. Also some other medicines can affect the way Ipratropium Nebulizer Solution works.
In particular, tell your doctor or pharmacist if you are taking any of the following:
- Medicines for breathing problems called 'beta-agonists' such as salbutamol
- Medicines for breathing problems called 'xanthine preparations' such as theophylline or aminophylline

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Ipratropium Nebulizer Solution.

Pregnancy and breast-feeding
Talk to your doctor before using this medicine if you are pregnant, likely to get pregnant or are breast-feeding.

Driving and using machines
You may feel dizzy, or have difficulty in focusing, or blurred vision while taking Ipratropium Nebulizer Solution. If this happens do not drive or use any tools or machines.

3. How to use Ipravent Respules
Always use Ipratropium Nebulizer Solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Follow these instructions to get the best results. If anything is unclear after reading this leaflet, ask your doctor or pharmacist.

How many dose units
Adults (including the elderly) and children over 12 years
- The usual dose is the contents of ½ to 1 single dose unit (250-500 micrograms), three to four times a day
- For acute attacks of breathlessness use 1 single dose unit (500 micrograms)
- If breathlessness does not go away or gets worse consult your doctor

Children under 12 years
- Not recommended for use

When children are using this medicine they must be supervised by a responsible adult.

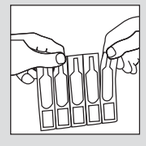
Do not swallow or give this medicine by injection.

Do not use your nebuliser to take Ipratropium Nebulizer Solution and 'disodium cromoglycate inhalation solutions' which have the preservative 'benzalkonium chloride' at the same time.

Do not use more than your doctor has told you
See your doctor straight away if:
- You feel that your medicine is not working as well as usual
- You need to use the nebuliser more than your doctor has recommended

Your doctor may need to check how well your medicine is working. In some cases your doctor may need to change your medicine.

How to use your nebuliser
Read through numbers 1 to 6 first, before starting to use your nebuliser.
1. Get your nebuliser ready by following the manufacturer's instructions. Ask your doctor if you are not sure how to use it.
2. • Open the pouch and remove the strip of unit dose vials.
   • Carefully separate a new dose unit from the strip. Do not use it if it is already open.



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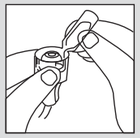
3. • Twist off the top.
• Always hold it upright while you do this

4. • Squeeze all the contents of the dose unit into the nebuliser chamber
• Your doctor will tell you if you need to use a different amount
• If you have also been prescribed a medicine called a 'short-acting beta2-agonist nebuliser solution' such as salbutamol the liquids can be mixed in the same nebuliser chamber
• If your doctor has told you that your medicine needs to be diluted, you will be given 'sterile sodium chloride 0.9%' solution. Your doctor will tell you how to do this



5. Use your nebuliser as directed by your doctor.
6. • After you have finished, dispose of any leftover medicine carefully
• Follow the manufacturer's instructions on how to clean your nebuliser
• It is important to keep your nebuliser clean

Use a mouthpiece or a tight fitting mask. If any of the liquid or mist accidentally gets into your eyes you may get painful, stinging or red eyes, dilated pupils, blurred vision, see colours or lights. If this happens, talk to your doctor for advice. If you get problems with your eyes at any other time, talk to your doctor for advice.

If you use more Ipratropium Nebulizer Solution than you should

If you use more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to use Ipratropium Nebulizer Solution
- If you forget a dose, use it as soon as you remember
- However, if it is nearly time for the next dose, skip the missed dose
- Do not use a double dose to make up for a forgotten dose

4. Possible side effects
Like all medicines, Ipratropium Nebulizer Solution can cause side effects, although not everybody gets them.

Stop using Ipratropium Nebulizer Solution and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:
- If after using Ipratropium Nebulizer Solution you are wheezy or have other difficulties in breathing, do not use any more (unless you have been told to by your doctor)
- Allergic reactions – the signs may include skin rash and itching (affects less than 1 in 100 people). In severe cases the signs include swelling of your mouth and face, sudden difficulties in breathing and reduction of your blood pressure. Tightening of your throat (affects less than 1 in 100 people)
- Palpitations (fast or uneven heart beats) or quickening of the heart rate (affects less than 1 in 100 people)
- Increased heart rate or irregular heart rhythm such as atrial fibrillation (affects less than 1 in 1000 people)

Stop using this medicine and see your doctor straight away if you have any of these side effects.

Other side effects include:
Common (affects less than 1 in 10 people)
- Headache, dizziness
- Dry mouth, feeling sick (nausea), stomach upset or discomfort
- Cough and throat irritation when you have just used Ipratropium Nebulizer Solution

Uncommon (affects less than 1 in 100 people)
- Itching, skin rash
- Unexpected tightness of the chest, swelling of the throat, dry throat
- Blurred vision, dilated pupils, glaucoma, painful, stinging, red or swelling of the eyes, see colours or lights
- Diarrhoea, constipation or being sick
- Mouth or lip sores
- Problems passing water (urine), especially if you already have problems passing urine

Rare (affects less than 1 in 1000 people)
- Difficulty focusing
- Nettle rash (urticaria)

If any of the liquid or mist accidentally gets into your eyes you may get painful, stinging or red eyes, dilated pupils, blurred vision, see colours or lights. If this happens, talk to your doctor for advice. If affected, do not drive or use any tools or machines. If you get problems with your eyes at any other time, talk to your doctor for advice.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store Ipratropium Nebulizer Solution
Do not use this medicine after the expiry date which is stated on the carton and the vial label. The expiry date refers to the last day of the month.
Store below 25**°C.**
Keep vials in the outer carton in order to protect from light.
Keep out of the sight and reach of children.

6. Further information
What Ipratropium Nebulizer Solution contain
Ipratropium Nebulizer Solution contains ipratropium bromide. Each single dose unit contains 500 micrograms of the active ingredient ipratropium bromide as Ipratropium Bromide monohydrate BP in 2 ml of solution.
The other ingredients are: sodium chloride, hydrochloric acid and water for injection.

What Ipratropium Nebulizer Solution looks like and contents of the pack
Carton containing 4 pouches each having combitray of 5 respules of 2 ml each.

Marketing authorisation holder and manufacturer

Leaflet revised: *February 2016*

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Paradoxical bronchospasm(2)	Uncommon
Laryngospasm	Uncommon
Pharyngeal oedema	Uncommon
Dry throat	Uncommon
Gastro-intestinal Disorders	
Dry mouth	Common
Nausea	Common
Gastro-intestinal motility disorder	Common
e.g. Diarrhoea	Uncommon
Constipation	Uncommon
Vomiting	Uncommon
Stomatitis	Uncommon
Skin and subcutaneous tissue disorders	
Rash	Uncommon
Pruritus	Uncommon
Urticaria	Rare
Renal and Urinary Disorders	
Urinary retention(3)	Uncommon

(1) ocular complications have been reported when aerolised ipratropium bromide, either alone or in combination with an adrenergic beta$_2$-agonist, has come into contact with the eyes – see section 4.4.

(2) As with other inhalation therapy, inhalation induced bronchoconstriction may occur with an immediate increase in wheezing after dosing. This should be treated straight away with a fast acting inhaled bronchodilator. Ipratropium Nebulizer Solution should be discontinued immediately, the patient assessed and, if necessary, alterative treatment instituted.

(3) the risk of urinary retention may be increased in patients with pre-existing urinary outflow tract obstruction.

Reporting of suspected adverse reactions
Reporting suspected adverse reaction after authorisation of the medicinal product is important. It allows continued monitoring of the benefit / risk balance of the medicinal product.

4.9 Overdose:
No symptoms specific to overdosage have been encountered. In view of the wide therapeutic window and topical administration of Ipratropium Nebulizer Solution, no serious anticholinergic symptoms are to be expected. As with other anticholinergics, dry mouth, visual accommodation disturbances and tachycardia would be the expected symptoms and signs of overdose.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:
ATC Code: R03BB01
Ipratropium is a quaternary ammonium compound with anticholinergic (parasympatholytic) properties. In nonclinical studies, it appears to inhibit vagally mediated reflexes by antagonising the action of acetylcholine, the transmitter agent released from the vagus nerve. Anticholinergics prevent the increase in intracellular concentration of Ca++ which is caused by interaction of acetylcholine with the muscarinic receptor on bronchial smooth muscle. Ca++ release is mediated by the second messenger system consisting of IP3 (inositol triphosphate) and DAG (diacylglycerol).

The bronchodilation following inhalation of Ipratropium Nebulizer Solution is induced by local drug concentrations sufficient for anticholinergic efficacy at the bronchial smooth muscle and not by systemic drug concentrations.

In clinical trials using metered dose inhalers in patients with reversible bronchospasm associated with chronic obstructive pulmonary disease significant improvements in pulmonary function (FEV1 increases of 15% or more) occurred within 15 minutes, reached a peak in 1-2 hours, and persisted for approximately 4 hours.

Preclinical and clinical evidence suggest no deleterious effect of Ipratropium Nebulizer Solution on airway mucous secretion, mucociliary clearance or gas exchange.

The bronchodilator effect of Ipratropium Nebulizer Solution in the treatment of acute bronchospasm associated with asthma has been shown in studies in adults and children over 6 years of age. In most of these studies ipratropium was administered in combination with an inhaled beta2-agonist.

5.2 Pharmacokinetic properties:
Absorption
The therapeutic effect of Ipratropium Nebulizer Solution is produced by a local action in the airways. Time courses of bronchodilation and systemic pharmacokinetics do not run in parallel.

Following inhalation, 10 to 30% of a dose is generally deposited in the lungs, depending on the formulation, device and inhalation technique. The major part of the dose is swallowed and passes through the gastro-intestinal tract.

The portion of the dose deposited in the lungs reaches the circulation rapidly (within minutes).

Cumulative renal excretion (0-24 hrs) of parent compound is approximated to 46% of an intravenously administered dose, below 1% of an oral dose and approximately 3 to 13% of an inhaled dose. Based on these data the total systemic bioavailability of oral and inhaled doses of ipratropium bromide is estimated at 2% and 7 to 28% respectively.

Taking this into account, swallowed dose portions of ipratropium bromide do not contribute significantly to systemic exposure.

Distribution
The drug is minimally (less than 20%) bound to plasma proteins. Nonclinical data indicate that the quarternary amine of the ipratropium ion does not cross the blood-brain barrier.

Biotransformation
After intravenous administration approximately 60% of the dose is metabolised, mainly by conjugation (40%), wheras after inhalation about 77% of the systemically available dose is metabolised by ester hydrolysis (41%) and conjugation (36%).

The known metabolites, which are formed by hydrolysis, dehydration or elimination of the hydroxy-methyl group in the tropic acid moiety, show very little or no affinity for the muscarinic receptor and have to be regarded as ineffective

Elimination
Ipratropium has a mean total clearance of 2.3 L/min and a renal clearance of 0.9 L/min.
In an excretion balance study cumulative renal excretion (6 days) of drug-related radioactivity (including parent compound and all metabolites) accounted for 72.1% after intravenous administration, 9.3% after oral administration and 3.2% after inhalation. Total radioactivity excreted via the faeces was 6.3% following intravenous application, 88.5% following oral dosing and 69.4% after inhalation. Regarding the excretion of drug-related radioactivity after intravenous administration, the main excretion occurs via the kidneys. The half-life for elimination of drug-related radioactivity (parent compound and metabolites) is 3.2 hours.

5.3 Preclinical safety data:
The toxicity of ipratropium bromide has been investigated extensively in the following types of studies: acute, subchronic and chronic toxicity, carcinogenicity, reproductive toxicity and mutagenicity via oral, intravenous, subcutaneous, intranasal and/or inhalation routes. Based on these toxicity studies, the probability of systemic anticholinergic side effects decreases in the following order:

intravenous > subcutaneous > oral > inhalation > intranasal.

Pre-clinically, ipratropium bromide was found to be well-tolerated. Two-year carcinogenicity studies in rats and mice have revealed no carcinogenic activity at doses up to approximately 1,200 times the maximum recommended human daily dose for intranasal ipratropium. Results of various mutagenicity tests were negative.

Studies to investigate the possible influence of ipratropium bromide on fertility, embryo-fetotoxicity, and peri-/postnatal development have been performed on mice, rats and rabbits. High oral levels, i.e. 1000 mg/kg/day in the rat and 125 mg/kg/day in the rabbit were maternotoxic for both species and embryo-/fetotoxic in the rat, where the fetal weight was reduced. Treatment-related malformations were not observed. The highest, technically feasible doses for inhalation of the metered dose aerosol, 1.5 mg/kg/day (human equivalent dose of 0.24 mg/kg/day) in rats and 1.8 mg/kg/day (human equivalent dose of 0.576 mg/kg/day) in rabbits, showed no adverse effects on reproduction.

These doses are 6- and 14-fold the maximum recommended human daily dose (MRHDD) of 2 mg or 0.04 mg/kg (based on a body weight of 50 kg).

6 PHARMACEUTICAL PARTICULARS:

6.1 List of excipients
Sodium Chloride, Hydrochloric acid, Water for Injection

6.2 Incompatibilities
Not Applicable

6.3 Shelf life
24 Months

6.4 Special precautions for storage
Store below 25°C.

6.5 Nature and contents of container
Carton containing 4 pouches each having combitray of 5 respules of 2 ml each.

6.6 Instructions for use, handling and disposal
NA

7 MARKETING AUTHORISATION HOLDER
--

8 MARKETING AUTHORISATION NUMBER (S)
--

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
--

10 DATE OF REVISION OF THE TEXT
February 2016

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PACKAGING DEVELOPMENT

Product Name: Ipravent	**Material No.: 21054132**	**Version:** 01	**Item:** Leaflet	**Date: 15-3-16**
Co-ordinator: Ganesh	**Artist: Vaibhav**	**Software:** Illustrator CC		
Fonts: ------				
Colours: BLUE WOOL TEST VALUE 5-8 (LIGHT FASTENING DATA) ■ Black				
INK: Oil based Ink from DIC OR MICRO				
Reference: New **Screen : # __**				
Links: NA				
2D Code : 21054132		**Design:** Folded		
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Actual Size: 360 x 240 mm		**Size after folding: 60 x 35 mma**		
Grain Direction : Parallel to length				
Reference / Instructions / Remark: NA				
Artwork Print Size: ☐ **actual** ☐ **scaled**				
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Checked by	**Artist**	**Cordinator**	**Section Head**	**File Copied by**	**file loaded in BCT HO**
Pharma Code	☐	☐			
2D Code	☐	☐			
Barcode	☐	☐			
Artwork	☐	☐			
Spell check	☐	☐		**Date:**	

NOTE TO THE PRINTER :

- Return approved artwork alongwith the proof.
- The proof must be verified against the approved hardcopy, should be certified and signed by an authorised QA person. The unsigned proof will not be accepted.
- Colour scheme must be as approved by packaging development co-ordinator.
- Any deviation must be brought to the notice of packaging development co-ordinator immediately.
- For any clarification, please contact packaging development co-ordinator immediately.