




Client:		Colours used:	Proportions used:
Project:	MOS0303 OTC IBUPROFEN TABLETS 400MG X 24 & X 48 PIL	 PMS BLACK	Calculation: Portrait
Item(s):	Leaflet		FOP text %: N/A
Category:	OTC		Image size (% of import): N/A
Date:	31.5.2024	 CUTTER	BOP Font size(pt): 9pt
			BOP Leading size (pt): 10pt
			EAN %: N/A

This scale measures 100mm when artwork is 100%



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Modifications:

Draft 1: Remove "BP"

<div>DRAFT COPY</div>	
<div>VERSION: 3 (FLAMINGO)</div>	
<div>DRAFT ISSUE: 1</div>	
<div>REASON FOR CHANGE: RFI UPDATE</div>	
<div>SUPPLIER ISSUE DATE: 31.5.2024</div>	<div> <div>Ibuprofen 400mg Tablets BP (FPL)</div> <div>P</div> </div> <div> <div>Leaflet Size : 155 x 440 mm</div> <div>MPLLIBU0400TBCOMFPLALM388V01</div> </div>

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	155 mm		
		Pharmaco-de Reading Direction XXXX	
(oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring. Breast-feeding Speak to your doctor or pharmacist before taking this medicine if you are breastfeeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.	<ul style="list-style-type: none"> A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis). <p>Other possible side effects Uncommon side effects (may affect up to 1 in 100 people)</p> <ul style="list-style-type: none"> Allergic reactions such as skin rashes (urticaria), itching, peeling Headache Indigestion, heartburn or feeling sick pains in your stomach (abdomen) or other abnormal stomach problems <p>Rare side effects (may affect up to 1 in 1000 people)</p> <ul style="list-style-type: none"> Diarrhoea, flatulence (wind), constipation and vomiting <p>Very rare side effects (may affect up to 1 in 10,000 people)</p> <ul style="list-style-type: none"> blood disorders resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion. drop in blood pressure stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis) liver problems <p>Not known:</p> <ul style="list-style-type: none"> worsening of asthma or bronchospasm swelling (oedema), high blood pressure, heart failure or attack worsening of colitis and Crohn's disease A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells). A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Ibuprofen if you develop these symptoms and seek medical attention immediately. See also section 2. skin becomes sensitive to light <p>Medicines such as ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.</p> <p>Reporting of side effects</p> <p>If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or by searching 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 medicine.</p>	<div>Pharma code XXXX</div>	
<p>Driving and using machines:</p> <p>Ibuprofen 400mg Tablets BP may make you feel dizzy or drowsy. If the tablets affect you in this way do not drive, operate machinery or do anything that requires you to be alert.</p> <p>Ibuprofen 400mg Tablets BP contain lactose, sucrose and sunset yellow (E110)</p> <p>This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.</p> <p>If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking these tablets.</p> <p>These tablets contain sunset yellow (E110), which can cause allergic-type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.</p> <p>3. HOW TO TAKE Ibuprofen 400mg Tablets BP:</p> <p>Always take Ibuprofen 400mg Tablets BP exactly as described in the leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.</p> <p>This medicine is for oral administration only.</p> <p>Take your Ibuprofen 400mg Tablets BP with or after food, with a glass of water.</p> <p>Ibuprofen 400mg Tablets BP should be swallowed whole and not chewed, broken, crushed or sucked to help prevent discomfort in the mouth or irritation in the throat. This product is intended for short term use only.</p> <p>The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.</p> <p>If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).</p> <p>You should not take Ibuprofen 400mg Tablets BP for longer than 10 days unless your doctor tells you to.</p> <p>Dosage:</p> <p>Dosage in adults, the elderly and children over 12 years: Take 1 tablet up to three times a day as required.</p> <p>Leave at least four hours between doses. Do not take more than 3 tablets in any 24 hour period. Do not give these tablets to children under 12 years old except on the advice of a doctor.</p> <p>In children and adolescents between 12 and 18 years this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.</p> <p>If you take more Ibuprofen 400mg Tablets BP than you should</p> <p>Seek medical attention IMMEDIATELY if you accidentally take too many tablets. If you have taken more this medicine than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advise on action to be taken. The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.</p> <p>If you forget to take your Ibuprofen 400mg Tablets BP</p> <p>Take them as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Never double up on a dose to make up for the one you have missed.</p> <p>4. POSSIBLE SIDE EFFECTS</p> <p>Like all medicines, Ibuprofen 400mg Tablets BP may cause side effects, although not everybody gets them.</p> <p>Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome</p> <p>The following side effects are very rare (may affect up to 1 in 10, 000 people), but if you suffer from any of the following at any time during your treatment STOP TAKING Ibuprofen 400mg Tablets BP and seek immediate medical help:</p> <ul style="list-style-type: none"> Signs of serious allergic reaction such as difficulties in breathing or unexplained wheezing, dizziness or faster heartbeat, severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (e.g.: Steven-Johnson syndrome), swelling of your face, tongue and/or throat, drop in blood pressure leading to shock Signs of intestinal bleeding such as passing blood in your faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds. Signs of aseptic meningitis (swelling of the protective membrane surrounding the brain) such as severe headache, high temperature, stiffness of the neck, nausea, vomiting, disorientation or intolerance to light. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected Signs of kidney problems such as: passing less or more urine, cloudy urine or blood in urine, pain in the back and/or swelling (particularly in the legs) Ibuprofen, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness. reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis]. Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome). 			
	<p>5. How to store Ibuprofen 400mg Tablets BP</p> <p>Keep this medicine out of the sight and reach of children.</p> <ul style="list-style-type: none"> Blister packaging: This medicinal product does not require any special storage conditions. Securitainer/Pharmacap bottles: Store below 25°C, Keep the bottle tightly closed. <p>Do not use after the expiry date shown on the package.</p> <p>6. CONTENTS OF THE PACK AND OTHER INFORMATION</p> <p>What does each tablet contain?</p> <p>Each tablet contains the active ingredient Ibuprofen 400mg. The tablets also contain: lactose monohydrate, maize starch, hypromellose, sodium starch glycollate, colloidal anhydrous silica, magnesium stearate, sucrose, purified talc, titanium dioxide (E171), carnauba wax, Colouring agent (sucrose, titanium dioxide E171, sunset yellow lake E110, erythrinsine Lake E127, sodium benzoate E211, purified water).</p> <p>What is in the pack?</p> <p>This product contains pink, shiny, biconvex, circular, sugar coated tablets.</p> <p>Ibuprofen 400mg Tablets BP are available in blister packs of 6, 12, 24, 48, 84 and 96 tablets. The product is also available in pots of 12 or 250 tablets.</p> <p>Not all the pack sizes may be marketed.</p> <p>Marketing Authorisation Holder: Flamingo Pharma (UK) Ltd. 1st Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex, HA1 2AX, United Kingdom</p> <p>Manufacturer: Flamingo Pharma (UK) Limited, The Bloc, 38 Springfield Way, Anlabay, Hull, HU10 6RJ, United Kingdom.</p> <p>If you would like this leaflet in different format information want to report any side effects please contact marketing authorization holder listed above</p> <p>This leaflet was last revised in October 2024.</p>		
	<p>P</p> <p>AL0323/3 AL0326/3 PL43461/0005</p>	<p>MPLLBU0400TCBM FPLALM38BVOI</p>	

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Colour Scheme : Black				Ref. Artwork : MPLL0001_V01_B	
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Artwork	Pkg. Development	Marketing	Regulatory	CQA	MAH
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