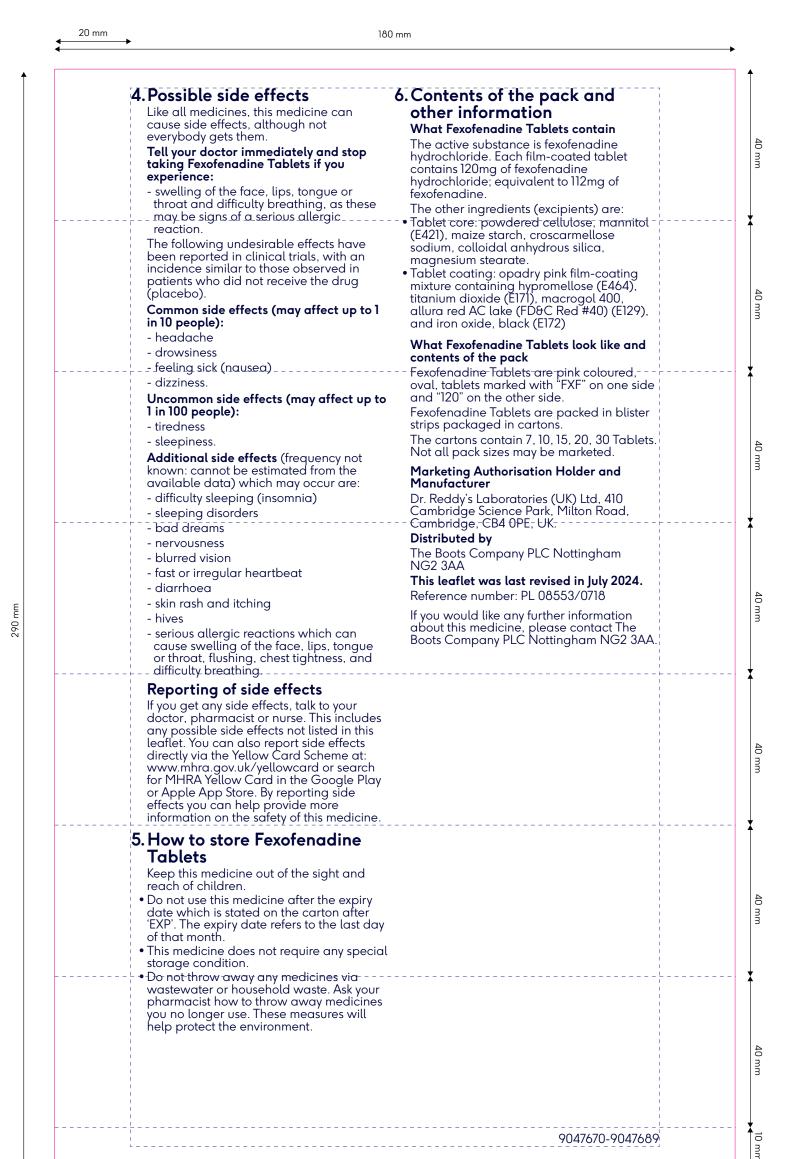
Date:06-08-2024:12:02

ARTWORK BRANDING

SYNERGIST JOB NO:

CATEGORY: BRAND: Boots Own Brand RANGE: Seasonal Healthcare PROJECT NO. PRODUCT TITLE: 120mg Film-coated Tablets WBA-6394-Boots Fexofenadine Hydrochloride 120mg Film-coated Tablets Leaflet PROOF NUMBER: PROOF DATE: 06/08/2024 ARTWORKER ITEM CODE: 9047670-9047689 COMPONENT CODE XXXX PHARMA CODE NO. XXXX BARCODE TYPE N/A BARCODE NO.: PACK TYPE: Leaflet **QUERIES FOR CLIENTS** FINISH TYPE: ANY 'CLIENT QUERY' BOXES WILL BE VISIBLE IN SUBSTRATE ED AND WILL BE AUTOMATICALLY REMOVED Paper ON APPROVAL OF THE ARTWORK. SUBSTRATE COLOUR NUMBER OF COLOURS PPROVAL BY THE ADMIN 'MASTER' APPROVER BRAILLE: WILL SIGNIFY THAT YOU ARE HAPPY TO PRINTING COLOURS PROCEED TO PRINT WITHOUT ACTION BEING AKEN WITH REGARDS TO THE CLIENT OUER TECHNICAL & NON-PRINTING SPECIAL FINISHES & FOILS **ARTWORK TEXT SIZES** LEAFLETS MIN 9PT, OTHER 7PT SUPPLIER CONTACT: hdavis@drreddys.cor PACK MOCK UP SUPPLIER DETAILS: 120mg Film-Coated Tablets Boots Fexofenadine HCl PIL (GSL PIL labelling text) PRINTER CONTACT: hdavis@drreddys.com PRINTER DETAILS: Internally approved Aluminium/PVC-PE-PVd0 blisters THIS SCALE MEASURES 50MM WHEN ARTWORK IS AT 100% PACK SIZE: 10 or 30 tablets UNDER NO CIRCUMSTANCES SHOULD THIS ARTWORK ALTERED WITHOUT PRIOR PERMISSION FROM WK360 **Artwork Only**



PACKAGE LEAFLET: INFORMATION FOR THE USER

Fexofenadine Hydrochloride 120mg Film-Coated Tablets

fexofenadine hydrochloride

leaflet as Fexofénadine Tablets. Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Fexofenadine Hydrochloride 120mg Film-Coated Tablets will also be referred to in this

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

• Keep this leaflet. You may need to read it

• Ašk your-pharmacist-if-you need moreinformation or advice. • This medicine is for your use only. Do not

pass it on to others. It may harm them, even if their signs of illness are the same • If you get any side effects, talk to your

doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4: You must talk to a doctor if you do not

feel better or if you feel worse after taking Fexofenadine Tablets.

What is in this leaflet 1. What Fexofenadine Tablets are and what they are used for 2. What you need to know before you take Fexofenadine Tablets

3. How to take Fexofenadine Tablets 4. Possible side effects 5. How to store Fexofenadine Tablets

6. Contents of the pack and other information

1. What Fexofenadine Tablets are and what they are used for Fexofenadine Tablets contain

fexofenadine hydrochloride, which is a non-drowsy antihistamine. Fexofenadine Tablets are used in adults and adolescents over 12 years of age to relieve the symptoms of allergic rhinitis (for example hayfever) such as sneezing, itchy, runny or blocked nose and itchy,

2. What you need to know before you take **Fexofenadine Tablets** Do not take Fexofenadine Tablets:

- red and-watery eyes. -

• If you are allergic to fexofenadine or any of the other ingredients of this medicine (listed in Section 6).

- Warnings-and precautions-----

Talk to your doctor or pharmacist before taking Fexofenadine Tablets if you: • have problems with your liver or kidneys. • have or ever had heart disease, since this kind of medicine may lead to a fast

or irregular heartbeat. • are elderly. If any of these apply to you, or if you are not sure, tell your doctor before taking

Fexofenadine Tablets.

Other medicines and Fexofenadine **Tablets** Tell your doctor or pharmacist if you are

taking, have recently taken or might take any other medicines.

• If you are taking apalutamide (a medicine to treat prostate cancer), as the effect of fexofenadine may be decreased. • Indigestion remedies containing aluminium

and magnesium may affect the action of Fexofenadine Tablets, by lowering the amount of medicinal product absorbed. It is recommended that you leave about 2 hours between the time that you take Fexofenadine Tablets and your indigestion

Pregnancy and breast-feeding-Fexofenadine Tablets should not be taken

during pregnancy and whilst breast-feeding unless advised by a doctor. Driving and using machines

Fexofenadine Tablets are unlikely to affect your ability to drive or operate machinery. However, you should check that these tablets do not make you feel sleepy or dizzy before driving or operating machinery. Fexofenadine Tablets also contain Allura

Red AC Lake, which may cause allergic For a full list of ingredients, please see

'Contents of the pack and other

3. How to take Fexofenadine **Tablets**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. For adults and children aged 12 years and

The recommended dose is one tablet (120mg) daily. Take your tablet with water before a meal. This medicine starts to relieve your symptoms within 1 hour and lasts for 24 hours. Fexofenadine Tablets are not recommended for children under 12

years of age. If you take more Fexofenadine Tablets than you should

If you take too many tablets, contact your doctor or the nearest hospital-emergency department immediately. Symptoms of an overdose in adults are dizziness, drowsiness, fatigue and dry mouth.

If you forget to take Fexofenadine Tablets Do not take a double dose to make up for a forgotten tablet. Take the next dose at the

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

PRODUCT LICENCE NO.: PL 08553/0718 WORDING REF:

PACK DETAILS:

VERSION NO.	DATE ISSUED	REASON FOR CHAN		
1	22/07/2024	New OLS product		

MAIN HEADINGS:	13pt
SUB HEADINGS:	9.3pt
BODY HEADINGS:	9.3pt

PRODUCT NAME:

STATUS:

QUERIES FOR CLIENTS

If Pharmacode is required please advise

Date:06-08-2024:12:02

ARTWORK

180 mm PACKAGE LEAFLET: INFORMATION FOR THE USER Fexofenadine Hydrochloride 120mg Film-Coated Tablets fexofenadine hydrochloride Fexofenadine Hydrochloride 120mg Film-Coated Tablets will also be referred to in this leaflet as Fexofénadine Tablets. Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Always take this medicine exactly as Other medicines and Fexofenadine described in this leaflet or as your Tablets doctor or pharmacist have told you. Tell your doctor or pharmacist if you are • Keep this leaflet. You may need to read it taking, have recently taken or might take any other medicines. • Ask your-pharmacist-if-you need more-• If you are taking apalutamide (a medicine information or advice. to treat prostate cancer), as the effect of • This medicine is for your use only. Do not fexofenadine may be decreased. pass it on to others. It may harm them, • Indigestion remedies containing aluminium even if their signs of illness are the same and magnesium may affect the action of Fexofenadine Tablets, by lowering the • If you get any side effects, talk to your amount of medicinal product absorbed. doctor or pharmacist. This includes any It is recommended that you leave about 2 possible side effects not listed in this hours between the time that you take Fexofenadine Tablets and your indigestion leaflet. See section 4. • You must talk to a doctor if you do not feel better or if you feel worse after taking Fexofenadine Tablets. Pregnancy and breast-feeding-Fexofenadine Tablets should not be taken What is in this leaflet 1. What Fexofenadine Tablets are and during pregnancy and whilst what they are used for breast-feeding unless advised by a doctor. 2. What you need to know before you take Driving and using machines Fexofenadine Tablets Fexofenadine Tablets are unlikely to affect 3. How to take Fexofenadine Tablets 4. Possible side effects your ability to drive or operate machinery. 5. How to store Fexofenadine Tablets However, you should check that these 6. Contents of the pack and other tablets do not make you feel sleepy or dizzy before driving or operating machinery. information Fexofenadine Tablets also contain Allura 1. What-Fexofenadine-Tablets Red AC Lake, which may cause allergic are and what they are used For a full list of ingredients, please see for 'Contents of the pack and other Fexofenadine Tablets contain fexofenadine hydrochloride, which is a 3. How to take Fexofenadine non-drowsy antihistamine. Fexofenadine Tablets are used in adults **Tablets** and adolescents over 12 years of age to Always take this medicine exactly as your relieve the symptoms of allergic rhinitis doctor has told you. Check with your doctor (for example hayfever) such as sneezing, itchy, runny or blocked nose and itchy, or pharmacist if you are not sure. For adults and children aged 12 years and - red and-watery eyes. -The recommended dose is one tablet 2. What you need to know (120mg) daily. Take your tablet with water before a meal. This medicine starts to before you take Fexofenadine Tablets relieve your symptoms within 1 hour and lasts for 24 hours. Fexofenadine Tablets are Do not take Fexofenadine not recommended for children under 12 Tablets: years of age. • If you are allergic to fexofenadine or any If you take more Fexofenadine Tablets of the other ingredients of this medicine than you should (listed in Section 6). If you take too many tablets, contact your doctor or the nearest hospital emergency Warnings and precautions ----department immediately. Symptoms of an Talk to your doctor or pharmacist before overdose in adults are dizziness, taking Fexofenadine Tablets if you: drowsiness, fatigue and dry mouth. • have problems with your liver or kidneys. If you forget to take Fexofenadine Tablets • have or ever had heart disease, since this kind of medicine may lead to a fast Do not take a double dose to make up for a forgotten tablet. Take the next dose at the or irregular heartbeat. • are elderly. If any of these apply to you, or if you are If you have any further questions on the use not sure, tell your doctor before taking of this medicine, ask your doctor or Fexofenadine Tablets. pharmacist.

The active substance is fevolenadine hydrochloride. Each film-coated table to taking fevolenadine Tablets if you experience: Swell your doctor immediately and stop taking fevolenaire force lips, stongue or swell and difficulty breathing, as these may be signs of a serious allergic reaction. The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patients who did not receive the drug (placebo). Common side effects (may affect up to 1 in 10 people): I headache - drawsiness I heeling sick (nausea) - drizniess. Uncommon side effects (may affect up to 1 in 10 people): I tiredness - sleepiness Additional side effects (frequency not known, connot be estimated from the available datab) which may occur are: - difficulty sleeping (insomina) - least or irregular heartbeat - drawnbeas - hervousness - blurred vision - last or irregular heartbeat - drizning of side effects (in to your doctor, pharmacist how to store Fexofe and in East of the pack - serious allergic reactions which can cause swelling of the face, lips, tongue arthroid flushing, chest tightness, and difficulty breating of the face of the content of the pack Reporting of side effects (in to your doctor, pharmacst or nurse. This includes leaffet, You can also report, side effects directly via the Yellow Card scheme at www.mhra.go.wuk/yellow.card or search for MHRA Yellow Card in the Google Play or Apple App Store By reporting side effects or content of the sole which is stated on the carton after EXF. The expiry date refers to the lost day of that month. Tablets Keep this medicine out of the sight and reach of children. To not throw away any medicines via wastewater or household waste. Ask your pharmacis thow to throw away my medicines would be a provinced and the contents of the sight and reach of children.	Tell your doctor immediately and stop taking Favorfenadine Tablets if you experience: - swelling of the face lips, tongue or swelling of difficulty broathing, as these may be signs of a serious allergic reaction. The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patients who did not receive the drug (placebo). Common side effects (may affect up to in 10 people): - headache - drowsiness - sleeling sick (nausea) - dizziness Uncommon side effects (may affect up to 1 in 100 people): - tiredness - sleepiness - sleepiness - sleeping disorders - sleeping disorders - sleeping disorders - baid direams - nervousness - nervousness - burred vision - fast or irregular heartbeat - diarrhoea - skin rash and itching - hives - serious allergic reactions which can cause swelling of the face. lips, tongue or throat, flushing, chest tightness, and difficulty breathing. Reporting of side effects if the face in this leaffect you can help provide more information on the safety of this medicine. Short was the safety of this medicine in the safety of this medicine course of this medicine out of the sight and reach of children. - Do not use this medicine out of the sight and reach of children Do not use this medicine out of the sight and reach of children Do not use this medicine out on the carton after EXP. The expiry date effects to the lost day woots woots woulknown out such of the lost day woots woots out she stored on the carton after EXP. The expiry date effects to the lost day woots woots woots out she stored on the carton after EXP. The expiry date effects woots woots of the lost day woots woots out she stored on the carton after EXP. The expiry date effects have been a conserved to the store out of the sight and reach of children Do not use this medicine out of the sight and reach of children Do no to use this medicine out of the sight and reach of children Do no tusten the safety of this medicine Do no tusten the safety of th	Like all medicines, this medicine can cause side effects, although not	6. Contents of the pack and other information What Fexofenadine Tablets contain	
may be signs of a serious allergic reaction. The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patients who did not receive the drug (placebo). Common side effects (may affect up to 1 in 10 people): - headache - drowsiness - feeling sick (nausea) - dizziness. Uncommon side effects (may affect up to 1 in 100 people): - tiredness - sleepiness. Additional side effects (may affect up to 1 in 100 people): - tiredness - sleepiness. Additional side effects (frequency not known cannot be estimated from the available data) which may occur are: - difficulty sleeping (insomnia) - sleeping disorders - bod dreams - nervousness - blurred vision - fast or irregular heartbeat - diarrhoea - skin rash and tiching - hives - serious allergic reactions which can cause swelling of the face, lips, tongue or throat, flushing, chest tightness, and difficulty breathing. Reporting of side effects - liv ug or any side effects (all to your obot or phermacist or nurse. This includes any possible side effects to list of in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhrn.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 sofety of this medicine. 5. How to store Fexofenadine - Tablets - Keep this medicine after the expiry date withich is stoted on the carton ofter of the month. • This medicine does not require any special storage condition. • Do not bus this medicine after the expiry date which is stoted on the carton ofter of the month. • This medicine does not require any special storage condition. • Do not bus this to those was a proper side offects of the carton ofter of the through and the carton ofter of the through of the through the carton ofter of the through of the carton ofter of the through of the carton ofter of the carton to the carton of t	may be signs of a serious allergic reaction. The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patients who did not receive the drug (placebo). Common side effects (may affect up to 1 in 10 people): - headache - drowsiness - feeling sick (nausea) dizziness. Uncommon side effects (may affect up to 1 in 100 people): - tiredness - seleping sick (nausea) dizziness. Uncommon side effects (may affect up to 1 in 100 people): - tiredness - sleepiness. Additional side effects (frequency not known: cannot be estimated from the ovaliable dato) which may occur are: - difficulty sleeping (insomnia) - sleeping disorders - bad drams - nervousness - blurned vision - fast or irregular heartbeat - diarrhoea - skin rash and itching - hives - serious allergic reactions which can cause swelling of the face, lips, tongue or throat. Hushing, chest tightness, and afficulty breathing. Reporting of side effects (lik to your doctor, pharmacist or nurse. This includes any possible side effects to tilts di nithis leaflet. You can not be special softs mercine information on the softey of this medicine. 5. How to store Fexofenadine Tablets Keep this medicine out of the sight and reach of children Do not use this medicine offer the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month. - Do no throw away any medicines wio washeader or household washe. Ask your pharmacist how to throw away medicines you no longer use. These measures will.	taking Fexofenadine Tablets if you experience: - swelling of the face, lips, tongue or	The active substance is fexofenadine hydrochloride. Each film-coated tablet contains 120mg of fexofenadine hydrochloride; equivalent to 112mg of	
cause swelling of the face, lips, tongue or throat, flushing, chest tightness, and difficulty breathing. 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. You can also report side effects directly via the Yellow Card Scheme at: 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 medicine. 5. How to store Fexofenadine Tablets Keep this medicine out of the sight and reach of children. • Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month. • This medicine does not require any special storage condition. • Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines	cause swelling of the face, lips, tongue or throat, flushing, chest tightness, and difficulty breathing. Reporting of side effects If you get any side effects If you get any side effects on listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 medicine. 5. How to store Fexofenadine Tablets Keep this medicine out of the sight and reach of children. • Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month. • This medicine does not require any special storage condition. • Do not throw away any medicines viawastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will	may be signs of a serious allergic reaction. The following undesirable effects have been reported in clinical trials, with an incidence similar to those observed in patients who did not receive the drug (placebo). Common side effects (may affect up to 1 in 10 people): - headache - drowsiness - feeling sick (nausea) - dizziness. Uncommon side effects (may affect up to 1 in 100 people): - tiredness - sleepiness. Additional side effects (frequency not known: cannot be estimated from the available data) which may occur are: - difficulty sleeping (insomnia) - sleeping disorders - bad dreams - nervousness - blurred vision - fast or irregular heartbeat - diarrhoea - skin rash and itching - hives	 Tablet core: powdered cellutose, mannitot (E421), maize starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate. Tablet coating: opadry pink film-coating mixture containing hypromellose (E464), titanium dioxide (E171), macrogol 400, allura red AC lake (FD&C Red #40) (E129), and iron oxide, black (E172) What Fexofenadine Tablets look like and contents of the pack Fexofenadine Tablets are pink coloured, oval, tablets marked with "FXF" on one side and "120" on the other side. Fexofenadine Tablets are packed in blister strips packaged in cartons. The cartons contain 7, 10, 15, 20, 30 Tablets. Not all pack sizes may be marketed. Marketing Authorisation Holder and Manufacturer Dr. Reddy's Laboratories (UK) Ltd, 410 Cambridge Science Park, Milton Road, Cambridge, CB4 OPE, UK. Distributed by The Boots Company PLC Nottingham NG2 3AA This leaflet was last revised in July 2024. Reference number: PL 08553/0718 If you would like any further information 	
5. How to store Fexofenadine Tablets Keep this medicine out of the sight and reach of children. • Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month. • This medicine does not require any special storage condition. • Do not throw away any medicines viawastewater or household waste. Ask your pharmacist how to throw away medicines	5. How to store Fexofenadine Tablets Keep this medicine out of the sight and reach of children. • Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month. • This medicine does not require any special storage condition. • Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will	or throat, flushing, chest tightness, and difficulty breathing. 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. You can also report side effects directly via the Yellow Card Scheme at: 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	Boots company i Le Nottingham NO2 JAA.	
'EXP'. The expiry date refers to the last day of that month. • This medicine does not require any special storage condition. • Do not throw away any medicines via	'EXP'. The expiry date refers to the last day of that month. • This medicine does not require any special storage condition. • Do not throw away any medicines via	 5. How to store Fexofenadine Tablets Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry 		
		 EXP'. The expiry date refers to the last day of that month. This medicine does not require any special storage condition. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines 		

		BRAND:	Boots Own Brand
		RANGE:	Seasonal Healthcare
		PROJECT NO.:	
		PRODUCT TITLE:	Fexofenadine Hydrochloride
		FILE NAME:	120mg Film-coated Tablets
		WBA-6394-Boots Fexofena Film-coated Tablets Leaflet	dine Hydrochloride 120mg
		PROOF NUMBER:	3
		PROOF DATE:	06/08/2024
		ARTWORKER:	Martyn
		ITEM CODE:	9047670-9047689
		COMPONENT CODE:	XXXX
		PHARMA CODE NO.:	XXXX
		BARCODE TYPE:	N/A
		BARCODE NO.:	
OHEDIE	S FOR CLIENTS	PACK TYPE:	Leaflet
QUENIE	FOR CLIENTS	FINISH:	
ANY 'CLIENT OUER	RY'BOXES WILL BE VISIBLE IN	FINISH TYPE:	
-	AUTOMATICALLY REMOVED	SUBSTRATE:	Paper
ON APPROV	AL OF THE ARTWORK.	SUBSTRATE COLOUR:	White
		NUMBER OF COLOURS:	1
APPROVAL BY THE	ADMIN'MASTER' APPROVER	BRAILLE:	Yes
WILL SIGNIFY T	HAT YOU ARE HAPPY TO		
PROCEED TO PRIN	IT WITHOUT ACTION BEING	PRINTING COLOURS	
TAKEN WITH REGA	ARDS TO THE CLIENT QUERY.		
		PMS 282 C	
	RK TEXT SIZES	TECHNICAL & NON-PRINTING	SPECIAL FINISHES & FOII
LEAFLETS N	MIN 9PT, OTHER 7PT		
MAIN HEADINGS:	13pt	Cutter Guides	
SUB HEADINGS:	9.3pt		
BODY HEADINGS:	9.3pt		1
PACI	K MOCK UP		
PRODUCT NAME:	Fexofenadine Hydrochloride 120mg Film-Coated Tablets		
PRODUCT LICENCE N	O.: PL 08553/0718		
WORDING REF:	Boots Fexofenadine HCl PIL (GSL PIL labelling text)		
STATUS:	Internally approved		
PACK DETAILS:	Aluminium/PVC-PE-PVdC		

SYNERGIST JOB NO:

Health

CATEGORY:

Artwork Only

THIS SCALE MEASURES 50MM WHEN ARTWORK IS AT 100%

QUERIES FOR CLIENTS

PACK SIZE:

If Pharmacode is required please advise

10 or 30 tablets

22/07/2024 New OLS product

REASON FOR CHANGE