FEDAC

PRODUCT DESCRIPTION:
Tablets : Light pink, round and flat tablets,8 mm diameter with score line and "DHA" logo.
Syrup : Clear mixture, yellow in colour, sweet taste with orange flavour.

COMPOSITION:

1) Tablets :	Triprolidine HCl BP	2.5 mg/tablet
	Pseudoephedrine HCl BP	60 mg/tablet
2) Syrup :	Triprolidine HCl BP	1.25 mg/5 ml
	Pseudoephedrine HCl BP	30 mg/5 ml

PRESERVATIVES:
Methyl hydroxybenzoate 0.15% w/v
Propyl hydroxybenzoate 0.015% w/v

PHARMACOLOGY:
Triprolidine is an antihistamine which competes with histamine for H-receptor sites on effector cells. It prevents but does not reverse responses mediated by histamine alone. Its anti-cholinergic actions provide a drying effect on the nasal mucosa. Pseudoephedrine acts on alpha-adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction. It shrinks swollen nasal mucous membrane, reduces tissue hyperemia, oedema and nasal congestion, and increases nasal airway patency. Also drainage of sinus secretions may be increased and obstructed eustachian ostia may be opened.

INDICATIONS:
Symptomatic treatment of nasal and respiratory congestion, common cold, acute sinusitis, allergic rhinitis.

RECOMMENDED DOSAGE:
Tablet : Adult : 1 tablet 3 times a day
Syrup : Adults and children over 12 years : 2 teaspoonfuls 3 times a day.
Children : 6 - 12 years : 1 teaspoonful,
2 - 5 years : ½ teaspoonful.
Doses to be taken 3 times a day.
Note : 1 teaspoonful is equal to 5ml.

CAUTION:
Not to be used in children less than 2 years of age.
To be used with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age.

ADVERSE EFFECTS:
Drowsiness, dryness of mouth, nervousness, restlessness, trouble in sleeping.

PRECAUTIONS:
Patients sensitive to one antihistamine or sympathomimetic may be sensitive to others. Triprolidine may cause drowsiness. If affected do not drive or operate machinery.

PHARMACODE AREA

AAAM7163- Triprolidine HCl/Pseudoephedrine HCl, Fedac 1.25/30 mg -, PIL, Singapore

GENERAL INFORMATION			
Proof Round:	2	**Dimensions:**	120x208 mm
Origination Date:	18.11.2020	**Manuf. site:**	Actavis Jakarta
Originated by:	GT	**Min pt size*:**	10 pt
Revision Date:	01.12.2020	**SAP Code:**	
Revised by:	GT		

TECHNICAL CHECK		
Date Sent:	27.11.2020	
Resent Date:		
Approval Date:	30.11.2020	
NON-PRINTING COLOURS	1. Profile	●
	2.	
	3.	

COLOURS/PLATES	
1. Black	●
2.	
3.	
4.	
5.	
6.	

teva
awstudio@tevapharm.com

*Note that smaller packaging dimensions may result in lower point size than your required font size.

Supplier Instructions Artwork, text and content must NOT be altered. The only exceptions to this are: bleeds, chokes, spreads or other adjustments required for print reproduction purposes only. If you have any difficulties please conact the Teva Artwork Team. We must receive a copy of the 3rd Party Vendros Proof before final approval can be made.

USE IN PREGNANCY:
There are no specific data on the use of triprolidine and pseudoephedrine during pregnancy. Caution should therefore be exercised by weighing the potential benefits against the possible risks to the foetus before prescribing the drug.

CONTRAINDICATIONS:
Individuals who are hypersensitive to any component in this product, patients with severe hypertension or severe coronary artery disease; patients who are taking or have taken MAOis within the preceding 2 weeks; patients with hyperthyroidism.

DRUG INTERACTIONS:
Concomitant use of Fedac with sympathomimetic agents or with MAOIs may cause a rise in blood pressure.
Pseudoephedrine may reverse the hypotensive activity of drugs which Interfere with sympathetic activity.
Triprolidine may enhance the drowsiness caused by sedative drugs and alcohol.

SYMPTOMS AND TREATMENT OF OVERDOSAGE:
Symptoms : Restlessness, delirium and muscle tremors.
Treatment: Give activated charcoal and then remove the drug by airway protected gastric lavage followed by catharsis.

AVAILABILITY:
Tablets : 10 x 10 x 10's blister pack
Syrup : 3.8 litres in high density polyethylene container with cap.
120 ml in amber glass bottle.

EXPIRY PERIOD AND STORAGE:
Do not use after the expiry date stated on the label. Store below 30°C and protect from light.

DATE OF REVISION : November 2020

For further information, please consult your physician or pharmacist

Manufactured by:
PT Actavis Indonesia
JL. Raya Bogor KM 28
Jakarta
Indonesia, 13710

PHARMACODE AREA

teva
AAAM7163

AAAM7163- Triprolidine HCl/Pseudoephedrine HCl, Fedac 1.25/30 mg -, PIL, Singapore

GENERAL INFORMATION			
Proof Round:	2	**Dimensions:**	120x208 mm
Origination Date:	18.11.2020	**Manuf. site:**	Actavis Jakarta
Originated by:	GT	**Min pt size*:**	10 pt
Revision Date:	01.12.2020	**SAP Code:**	
Revised by:	GT		

TECHNICAL CHECK		COLOURS/PLATES	
Date Sent:	27.11.2020	1. Black	●
Resent Date:		2.	
Approval Date:	30.11.2020	3.	
NON-PRINTING COLOURS	1. Profile ●	4.	
	2.	5.	
	3.	6.	

teva
awstudio@tevapharm.com

*Note that smaller packaging dimensions may result in lower point size than your required font size.

Supplier Instructions Artwork, text and content must NOT be altered. The only exceptions to this are: bleeds, chokes, spreads or other adjustments required for print reproduction purposes only. If you have any difficulties please conact the Teva Artwork Team. We must receive a copy of the 3rd Party Vendros Proof before final approval can be made.