

	Client		Color : BLACK 	Finishing :
	Product	Dirsliip FEDAC MY		
	Dimension	120 x 208mm		
	Code	41311-03		
	Material			
	Date			

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 :	Tripolidine HCl BP	2.5mg/tablet
	Pseudoephedrine HCl BP	60mg/tablet
2) Syrup :	Tripolidine HCl BP	1.25mg/5ml
	Pseudoephedrine HCl BP	30mg/5ml
	Preservatives:	
	Methyl hydroxybenzoate	0.15% w/v
	Propyl hydroxybenzoate	0.015% w/v



PHARMACOLOGY:

Tripolidine is an antihistamine which competes with histamine for H₁-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 : Adults : 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 teaspoon.
Doses to be taken 3 times a day.

Note: 1 teaspoonful is equal to 5ml.

Route of administration : Oral

WARNING:

When Fedac Syrup is used for treatment of cough and cold:
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. Tripolidine may cause drowsiness. If affected do not drive or operate machinery.

USE IN PREGNANCY:

There are no specific data on the use of tripolidine 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. Tripolidine 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 : 60ml in high density polyethylene container with cap.
120ml 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: June 2022

For further information, please consult your physician or pharmacist.

Manufactured by:
PT Actavis Indonesia
Jl. Raya Bogor Km. 28, Kelurahan Pekayon, Kecamatan Pasar Rebo
Kota Jakarta Timur, Provinsi DKI Jakarta, Indonesia


Actavis
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