

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

'Fam-Lax Phenolphthalein' Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents :

	Quantity per tablet
Yellow Phenolphthalein USP	120 mg
Powdered Rhubarb BP	27.5 mg

3 PHARMACEUTICAL FORM

Brown circular tablets embossed with the letter T.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic relief from constipation.

4.2 Posology and method of administration

'Fam-Lax Phenolphthalein' Tablets are for oral administration.

Adults, The Elderly and Children over 12 years of age :

Half to 1 tablet daily to be taken at bedtime.

Children under 12 years of age : Not recommended.

Directions : The tablet may be chewed or crushed and taken with the aid of water, milk or fruit juice.

4.3 Contraindications

There are no known contra-indications.

4.4 Special warnings and precautions for use

Prolonged use should be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

There are no known interactions.

4.6 Fertility, Pregnancy and lactation

There are no contra-indications to the administration of 'Fam-Lax Phenolphthalein' Tablets during pregnancy and lactation, however as with all drugs, therapy during the first trimester of pregnancy should be avoided.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Phenolphthalein Abdominal cramps may occasionally occur. Allergic reactions have been reported. Cardiac and respiratory distress and renal damage have also been reported.

4.9 Overdose

Overdosage can result in diarrhoea with excessive loss of water and electrolytes, particularly potassium. Treat symptomatically. There is also the possibility of developing an atonic non-functioning colon.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Phenolphthalein is an irritant purgative, usually taken at night to act in the morning.

Rhubarb is a mild anthraquinone purgative. It differs from other anthraquinone purgatives in that it exerts an astringent action after purgation.

5.2 Pharmacokinetic properties

Phenolphthalein is a diphenylmethane stimulant laxative. Up to 15% of phenolphthalein given by mouth is absorbed. Enterohepatic circulation occurs and the active glucuronide is excreted in the bile.

Some excretion occurs in the urine. Phenolphthalein usually has an effect within six to eight hours but because of enterohepatic circulation its action may continue for several days. Rhubarb is an anthraquinone laxative. The active anthraquinones are liberated into the colon from the glycosides by colonic bacteria and an effect usually occurs 6 to 12 hours after administration. There is some absorption of the anthraquinones following hydrolysis. Excretion occurs in the urine and the faeces and also in other secretions including milk.

5.3 Preclinical safety data

No remarks.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Icing Sugar, Cocoa Powder, Powdered Acacia BP, Vanillin Ph.Eur., Peppermint Oil Ph.Eur., Stearic Acid BP, Purified Talc Ph.Eur.

6.2 Incompatibilities

None known.

6.3 Shelf life

Five years from the date of manufacture.

6.4 Special precautions for storage

Five years from the date of manufacture.

6.5 Nature and contents of container

For 12, 30 and 36 tablet pack sizes - strip foil packaging having the following specifications:

a) 0.03 mm Aluminium Foil, 0.02 mm Surlyn

or

b) 40 G SM Paper 12 0 SM Polythene
0.008 mm Aluminium Foil 25 G SM Paper

Each strip contains six tablets. Two, five or six strips are packed into an outer cardboard box.

For 9 tablet pack size - metal plate tin containing nine tablets. The tin is packed into an outer cardboard box.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00551/0226

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

22nd May 1996

10 DATE OF REVISION OF THE TEXT

07/03/2014