1.6 Product Information

1.6.1 Prescribing Information (Summary of Product Characteristics)

Note:

1) We do not have a package insert in the SmPc format as yet. We are still waiting for approval thereof from the South African Health Products Regulatory Authority (SAHPRA).
2) We also do not have an approved patient information leaflet (PIL) yet. This is also pending SAHPRA approval.
3) We have however included the currently approved South African Package Insert which is also what can be found in the product.

BENYLIN® DRY COUGH

SCHEDULING STATUS:

S2

PROPRIETARY NAME (AND DOSAGE FORM):

BENYLIN® Dry Cough (syrup)

COMPOSITION:

Each 5 ml syrup contains:

Dextromethorphan hydrobromide		15 mg
Preservative:	Sodium Benzoate	0,5 % m/v
Sugar-free	Alcohol-free	

Other ingredients: sorbitol, glycerine, propylene glycol, sodium citrate hydrous, sodium carboxymethylcellulose, sodium cyclamate, citric acid hydrous, water purified, saccharin sodium, menthol , D & C YELLOW NO. 10, F D & C RED NO. 40, F D & C BLUE NO. 1 and raspberry flavour.

PHARMACOLOGICAL CLASSIFICATION:

A: 10.1 Antitussives and Expectorants

PHARMACOLOGICAL ACTION:

Dextromethorphan is a centrally acting cough suppressant. It acts by elevating the threshold for coughing.

INDICATIONS:

BENYLIN® Dry Cough is indicated for the symptomatic relief of non-productive cough.

CONTRA-INDICATIONS:

Hypersensitivity to dextromethorphan or to any of the ingredients.
Contra-indicated in patients with asthma and hepatic dysfunction.
BENYLIN® Dry Cough should not be given to children under 5 years of age.
Safety in pregnancy and lactation has not been established.
(SEE PREGNANCY AND LACTATION)

WARNINGS:

BENYLIN® Dry Cough should not be taken for persistent cough, which occurs with smoking, asthma, emphysema or where cough is accompanied by excessive secretions except under the advice and supervision of a doctor. A persistent cough may be a sign of a serious condition. If cough persists for more than one week,

tends to recur or is accompanied by high fever, rash or persistent headache, consult a doctor.

INTERACTIONS:

Concomitant administration with central nervous system depressants may potentiate central nervous system depressant effects. Concurrent use with monoamine oxidase inhibitors may cause excitation, hypertension and hyperpyrexia.

PREGNANCY AND LACTATION:

Pregnancy:

BENYLIN® Dry Cough is not recommended in pregnancy.

Lactation:

BENYLIN® Dry Cough should not be used by nursing mothers, as there is no information to support the secretion of dextromethorphan into breast milk

DOSAGE AND DIRECTIONS FOR USE:

Adults:	One medicine measure (5 ml) every four hours, or two medicine measures (10 ml) every six to eight hours.
Children 5 to 12 years:	Half to one medicine measure (2,5 ml – 5 ml) every six to eight hours.
Children below 5 years of age:	Not recommended

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Dextromethorphan may cause dizziness, gastro-intestinal disturbances, drowsiness, nausea and vomiting, and stomach pain. Respiratory depression is expected to occur at very high doses.

Special Precautions:

Persistent coughs should be investigated by a doctor for the possible underlying cause.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Excitation and confusion may occur after overdosage.

Treatment:

Symptomatic and supportive.

IDENTIFICATION:

Dark brown syrup with a faint odour of menthol and raspberries.

PRESENTATION:

Bottles containing 100 ml and 200 ml, with a plastic measuring cup.

STORAGE INSTRUCTIONS:

Store in a cool place (at or below 25ºC).

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Z/10.1/5

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Johnson & Johnson (Pty) Ltd.
241 Main Road
RETREAT
7945
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

02 March 2012

EXPORT REGISTRATION DETAILS

Botswana:	BOT9800287 S3
Ghana:	FDA/SD.133-1062
Kenya:	H2001/0370
Malawi:	PMPB/PL 353/5
NAFDAC Reg. No.:	B4-7110
Tanzania:	TAN 00,927 R05F WAR
Uganda:	1651/25/97
Zambia:	082/047 P
Zimbabwe:	2000/22.2.5/3769 P