Product Information Leaflet

ViralChoice® Cough Syrup.

Winthrop Group sanofi aventis PHARMACHOICE HEALTHCARE

PROPRIETARY NAME (AND DOSAGE FORM)
ViralChoice® Cough Syrup.

COMPOSITION
Each 5 ml contains:
Thyme liquid extract
(Thymus vulgaris) 0.25 mg/5 ml
Primula root liquid extract
(Primula officinalis) 0.125 mg/5 ml

Contains 5 % alcohol per 5 ml syrup.
It contains sucrose and invert syrup.

PHARMACOLOGICAL CLASSIFICATION
A 32.2 Other: Complementary medicine

INDICATIONS
ViralChoice® Cough Syrup is a herbal preparation used in colds of the respiratory tract.
ViralChoice® Cough Syrup is used for the treatment of symptoms of acute bronchitis and in colds of the respiratory tract with mucous secretion.

CONTRA-INDICATIONS
Hypersensitivity to any of the ingredients.

WARNINGS
Consult a healthcare practitioner before use if you are using any other medication even those not prescribed. Consult your doctor immediately if the complaints are persisting or in the event of dyspnoea (shortness of breath), fever above 39 °C, purulent or bloody sputum.
Please consult your doctor when you know about any intolerance to specific sugars before taking ViralChoice® Cough Syrup.

INTERACTIONS
Supplemental intake of certain ingredients may interfere with certain medication, other supplements and herbal products, diseases, conditions, laboratory tests and foods.

PREGNANCY AND LACTATION
The wide use of thyme as a medicine or as a food has not yielded any signs that would involve a risk for pregnancy and breast-feeding. Specific results from investigations into thyme and primula root during pregnancy and breast-feeding are not available.
Avoid use during pregnancy and lactation as safety has not been established (Ref 1).

DOSAGE AND DIRECTIONS FOR USE
Always take ViralChoice® Cough Syrup exactly as instructed in this leaflet.
If you have any uncertainty you must discuss this with your doctor or pharmacist.
Unless otherwise prescribed by the doctor, the usual dosage is:

Age	Single dose	Daily dose
Children from 6 years, adolescents and adults	One and half a medicine measureful (7,5 ml) 4 times daily	6 medicine measureful (30 ml)

Shake the bottle before use.
Hit the bottom of the bottle to facilitate pouring if so required.
Take ViralChoice® Cough Syrup distributed over the day at regular intervals. The duration of the application is not limited. However, consider the information given in the Side-effects sections of this leaflet.
Tell your doctor or pharmacist if you have the impression that the effect of ViralChoice® Cough Syrup is too strong or too weak.
In case you have not taken enough ViralChoice® Cough Syrup or forgotten an application take the dose as soon as possible, then continue as instructed. However, if you have forgotten to take ViralChoice® Cough Syrup a whole day, do not take the missing dose, but continue as usual the next day.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS
On very rare occasions hypersensitivity reactions may occur, such as cutaneous rash or nettle rash (exanthema, urticaria) as well as swellings of the face, the mouth and/or the throat (Quincke's oedema) associated with shortness of breath (dyspnoea). On very rare occasions gastro-intestinal complaints may occur, such as nausea, vomiting and diarrhoea, and very rarely convulsions. Stop taking ViralChoice® Cough Syrup when you notice any sign of hypersensitivity.
Tell your doctor immediately who will decide on the severity and take any measures that might be necessary.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
There are no known cases of overdosage. Treatment should be supportive and symptomatic.

IDENTIFICATION
Syrupy liquid.

PRESENTATION
100 ml, 200 ml and 250 ml bottle.
ViralChoice® Cough Syrup contains extracts of plant origin: occasionally sedimentations of flocculation may appear which do not affect the efficacy of the preparation.

STORAGE INSTRUCTIONS
Store below 25 °C in a cool, dry place.
In-use storage
Once the bottle has been opened, the syrup may be used for 6 months when stored below 25 °C.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER
To be allocated.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE
Winthrop Pharmaceuticals (Pty) Ltd
2 Bond Street,
Midrand,
Gauteng.
1685

DATE OF PUBLICATION OF THIS PACKAGE INSERT
November 2009

Referencing: Ref 1 – Natural Medicine Comprehensive data base. (2006)

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Produk Inligtingspamflet

ViralChoice® Hoesstroop

EIENDOMSNAAM (EN DOSEERVORM)
ViralChoice® Hoesstroop

SAMESTELLING
Elke 5 ml bevat:

Tiemie vloeibare ekstrak (Thymus vulgaris)	0.25 mg/5 ml
Sleutelblomwortel vloeibare ekstrak (Primula officinalis)	0.125 mg/5 ml

Bevat 5% alkohol per 5 ml stroop.
Bevat sukrose en invertstroop.

FARMAKOLOGIESE KLASSIFIKASIE
A 32.2 Ander. Komplementêre medisyne.

INDIKASIES
ViralChoice® Hoesstroop is 'n kruiepreparaat wat vir verkoues van die lugweg gebruik word.
ViralChoice® Hoesstroop word gebruik vir die behandeling van simptome van akute brongitis en verkoues van die lugweg met slymafskeidings.

KONTRA-INDIKASIES
Hipersensitiwiteit teenoor enige van die bestanddele.

WAARSKUWINGS
Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik indien jy enige ander medikasie neem, selfs dié wat nie voorgeskryf word nie.
Raadpleeg jou dokter dadelik indien die klagtes voortduur of indien dispnee (kortasem), koors bokant 39°C en etterige of bloederige sputum voorkom.
Raadpleeg jou dokter asseblief as jy bewus is van enige intoleransie teenoor spesifieke suikers, voordat jy ViralChoice® Hoesstroop neem.

INTERAKSIES
Aanvullende gebruik van sekere bestanddele mag met sekere medikasies, ander aanvullings en kruiemiddels, siektes, toestande, laboratoriumtoetse en voedsel, inmeng.

SWANGERSKAP EN LAKTASIE
Die wye gebruik van tiemie as 'n medisyne of 'n voedsel het geen bewyse opgelewer dat dit 'n risiko vir swangerskap en borsvoeding sou inhou nie. Spesifieke resultate van ondersoeke met betrekking tot tiemie en sleutelblomwortel tydens swangerskap en borsvoeding is nie beskikbaar nie.

Vermy gebruik tydens swangerskap en laktasie omdat veiligheid nie vasgestel is nie (Verwys. 1).

DOSIS EN GEBRUIKSAANWYSINGS
Neem ViralChoice® Hoesstroop altyd presies volgens die instruksies in hierdie pamflet.
Indien jy enige onsekerheid ondervind, moet jy dit met jou dokter of apteker bespreek.
Tensy andersins deur die dokter voorgeskryf, is die gebruiklike dosis:

Ouderdom	Enkeldosis	Daaglikse dosis
Kinders vanaf 6 jaar, adolessente en volwassenes	Een en 'n halwe medisynemates (7,5 ml) 4 keer daagliks	6 medisynemates (30 ml)

Skud die bottel voor gebruik.
Stamp die onderkant van die bottel om uitgieting te bevorder indien nodig.
Neem ViralChoice® Hoesstroop versprei oor die dag met gereelde tussenposes. Die duur van toediening is nie beperk nie. Die inligting wat in die Newe-effekte gedeelte van hierdie pamflet gegee word, moet egter in ag geneem word.
Vertel jou dokter of apteker indien jy onder die indruk verkeer dat die effek van ViralChoice® Hoesstroop te sterk of te swak is.
Indien jy nie genoeg ViralChoice® Hoesstroop geneem het nie, of 'n dosis vergeet het, neem die dosis so gou as moontlik, en gaan dan voort volgens instruksies. Indien jy egter vergeet het om ViralChoice® Hoesstroop vir 'n hele dag te neem, moenie die ontbrekende dosis neem nie, maar gaan net voort soos gebruiklik die volgende dag.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS
In baie seldsame gevalle mag hipersensitiwiteitsreaksies voorkom, soos veluitslag of netelroos (eksanteem, urtikarie), asook swelling van die gesig, die mond en/of die keel (Quincke se edeem) geassosieer met kortasemheid (dispnee). In baie seldsame gevalle mag gastroïntestinale klagtes voorkom, soos naarheid, braking en diarree, en in besonder seldsame gevalle, konvulsies. Staak die inname van ViralChoice® Hoesstroop sodra jy van enige teken van hipersensitiwiteit bewus word.
Vertel jou dokter onmiddellik. Die dokter sal oor die erns besluit en enige maatreëls wat nodig mag wees, toepas.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Geen gevalle van oordosering is bekend nie. Behandeling behoort ondersteunend en simptomaties te wees.

IDENTIFIKASIE
Stroperige vloeistof.

AANBIEDING
100 ml, 200 ml en 250 ml bottel
ViralChoice® Hoesstroop bevat ekstrakte van plantaardige oorsprong: soms mag sedimentasies van flokkulasie verskyn, wat nie die doeltreffendheid van die preparaat beïnvloed nie.

BEWARINGSINSTRUKSIES
Bewaar benede 25 °C op 'n koel, droë plek.
Bewaring tydens gebruik
Nadat die bottel opgemaak is, mag die stroop vir 6 maande gebruik word, mits dit benede 25 °C bewaar word.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER
Sal toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
Winthrop Pharmaceuticals (Edms) Bpk
Bondstraat 2,
Midrand,
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1685

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