Front Side

470 mm

435 mm

SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

VIRULATE (film-coated tablets)

Hypersensitivity to abacavir (see also section 4.8)
Abacavir is associated with a risk for hypersensitivity reactions (HSR) characterised by fever and/or rash with other symptoms indicating multi-organ involvement. HSR can be life-threatening and may be fatal when not managed appropriately. The risk for abacavir HSR to occur is significantly increased for patients who test positive for the HLA-B*5701 allele. However, abacavir HSRs have been reported at a lower frequency in patients who do not carry this allele.
In clinical studies, conducted before the introduction of screening for the HLA-B*5701 allele, approximately 5 % of subjects receiving abacavir developed a hypersensitivity reaction. In some cases, this has proved fatal.

Risk Factors:
Studies have shown that carriage of the HLA-B*5701 allele is associated with a significantly increased risk of a hypersensitivity reaction to abacavir. In the prospective study CNA106030 (PREDICT-1), use of pre-therapy screening for the HLA-B*5701 allele and subsequently avoiding abacavir in patients with this allele reduced the incidence of clinically suspected abacavir hypersensitivity reactions from 7,8 % (66 of 847) to 3,4 % (27 of 803) (p < 0,0001) and the incidence of hypersensitivity reactions confirmed by skin patch testing from 2,7 % (23 of 842) to 0,0 % (0 of 802) (p < 0,0001). Based on this study it is estimated that 48 % to 61 % of patients with the HLA-B*5701 allele will develop a hypersensitivity reaction during the course of abacavir treatment compared with 0 % to 4 % of patients who do not have the HLA-B*5701 allele.
It is recommended that any HIV-infected patient without prior exposure to abacavir be screened for HLA-B*5701 allele. Screening is recommended prior to re-initiation of abacavir in patients of unknown HLA-B*5701 status who have previously tolerated abacavir (see *Special considerations following an interruption of VIRULATE therapy*). Use of abacavir in patients known to carry the HLA-B*5701 allele is not recommended.
In any patient treated with abacavir, the clinical diagnosis of suspected hypersensitivity reaction must remain the basis of clinical decision making. Even in the absence of the HLA-B*5701 allele, [illegible]

[illegible]

VIRULATE
(film-coated tablets)

Back Side

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

VIRULATE 600 / 300 (Film-coated tablet)
Abacavir 600 mg and lamivudine 300 mg
Sugar free

IMPORTANT - HYPERSENSITIVITY REACTION
VIRULATE contains abacavir. Patients taking VIRULATE may develop a hypersensitivity reaction (serious allergic reaction). It is essential you read the information on this reaction in the "Take special care with VIRULATE" section of this leaflet. There is also an Alert Card included in the VIRULATE pack, to remind you and medical staff about VIRULATE hypersensitivity. This card should be removed from the pack and kept with you at all times. The text on this card is shown below.
Patients taking VIRULATE may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening if treatment with VIRULATE is continued.
CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking VIRULATE if:
1) you get a skin rash OR
2) you get one or more symptoms from at least TWO of the following groups:
- fever
- shortness of breath, sore throat or cough
- nausea or vomiting or diarrhoea or abdominal pain
- severe tiredness or achiness or generally ill feeling.

If you have discontinued VIRULATE due to a hypersensitivity reaction, **YOU MUST NEVER TAKE VIRULATE, or any other medicine containing abacavir again, as within hours you may experience a life-threatening lowering of your blood pressure or death.**

Read all of this leaflet carefully before you start taking VIRULATE
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- VIRULATE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet
1. What VIRULATE is and what it is used for
2. What you need to know before you take VIRULATE
3. How to take VIRULATE
4. Possible side effects
5. How to store VIRULATE

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470 mm

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MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

APPROVED By Carina Page at 2:21 pm, Jun 30, 2023

APPROVED By Mmaditaba Mokoena at 7:21 am, Jun 30, 2023

1. Product: VIRULATE (Abacavir / Lamivudine 600 mg / 300 mg)	
2. Country: South Africa - UNICORN	3. Packaging component: Package Insert & Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 470 (L) x 435 (W) mm
9. Design / Style: Booklet Type	10. Item code No.: PM04142801
11. Artwork has been made: Actual Size	12. Pharma code No.: 32879 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision No: 00	16. AW File name:X:\Abacavir 600 mg and Lamivudine 300 mg Tablets\UNICORN\ABACAVIR-LAMIVUDINE 600MG-300 MG PI & PIL - PM04142801.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
6/07/23	Vanita Rajool	01/07/23	04/07/23	04/07/23	5/07/23

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

QA 06/07/23

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa Unicorn	PM04142801		

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