

ASENAPINE MALEATE - asenapine maleate tablet

Centaur Pharmaceuticals Private Limited

These highlights do not include all the information needed to use ASENAPINE SUBLINGUAL TABLETS safely and effectively. See full prescribing information for ASENAPINE SUBLINGUAL TABLETS.

Initial U.S. Approval: 2009

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

GTIN: 0064330625013
S.N. XXXXXXXXXX
EXP. MM/YYYY
LOT: XXXXXXXXX
GTIN, S.N., EXP. & LOT, Details along with variable data shall be over coded with 2D during packing.

NDC 64330-625-01

Asenapine Sublingual Tablets

2.5 mg

For opening and use instructions, see other side.

Black Cherry Flavor

Phenylketonurics: Contains Phenylalanine 0.17 mg Per Tablet.

**For sublingual (under the tongue) use only.
Do not split, cut or crush tablet.
Do not chew or swallow tablet.**

Rx only
60 (6x10) Unit-dose tablets

Centaur

Each sublingual tablet contains:
2.5 mg asenapine (as maleate), aspartame, colloidal silicon dioxide, croscopolidone, low substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, povidone and black cherry flavor (components are nature identical flavorings, natural flavoring substances, natural flavoring complexes, maize maltodextrin and moisture).

Dosage: See package insert.

Storage: Store at 20° to 25° C (68° to 77° F); excursions permitted between 15° to 30° C (59° to 86° F) [See USP Controlled Room Temperature].

Warning: Keep this and all medications out of reach of children.

- 1 Hold the blister as such that it faces the printed blister foil side and tear along the perforation marked on the blister to separate.
- 2 Peel the paper where "PEEL & PUSH" is given on the blister to expose foil.
- 3 Gently PUSH tablet through foil and take the tablet. Do not split, cut or crush the tablet.
- 4 Place the whole tablet under tongue and allow it to dissolve completely.
- 5 Do not eat or drink for 10 minutes

IMPORTANT:

- For sublingual (under the tongue) use only.
- Do not remove tablet until ready to administer.
- Use dry hands when handling tablet.

10 minutes

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2.5 mg

Black Cherry Flavor

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60 (6x10) Unit-dose tablets

Rx only

MH/DRUGS/IPD/182

Manufactured by:
Centaur Pharmaceuticals Pvt. Ltd,
Pune 411057 INDIA.

Manufactured For:
Centaur Pharmaceuticals Pvt. Ltd,
'Centaur House', Near Grand Hyatt,
Shanti Nagar, Vakola, Santacruz (East)
Mumbai, Maharashtra, 400 055, INDIA.

Rev: 11/2020

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ASENAPINE MALEATE

asenapine maleate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64330-625
Route of Administration	SUBLINGUAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASENAPINE MALEATE (UNII: CU9463U2E2) (ASENAPINE - UNII:JKZ19V908O)	ASENAPINE	2.5

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE (120 .MU.M) (UNII: 68401960MK)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	3mm
Flavor	CHERRY (black cherry)	Imprint Code	B;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64330-625-01	60 in 1 BOX; Type 0: Not a Combination Product	12/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205960	12/10/2020	

Labeler - Centaur Pharmaceuticals Private Limited (918629361)**Registrant** - Centaur Pharmaceuticals Private Limited (918629361)**Establishment**

Name	Address	ID/FEI	Business Operations
Centaur Pharmaceuticals Private Limited		675596622	MANUFACTURE(64330-625) , ANALYSIS(64330-625) , PACK(64330-625)

