יוני 2025

רופא/ה רוקח/ת נכבד/ה,

חברת פאדאגיס מבקשת ליידע אתכם על עדכון עלון לרופא של התכשירים :

נבלבין TM 20 מ"ג כמוסות	NAVELBINE® 20mg Capsule
נבלבין TM 30 מ"ג כמוסות	NAVELBINE® 30mg Capsule

החומר הפעיל בתכשיר וחוזקו :

NAVELBINE® 20mg : Vinorelbine (as tartrate) 20mg
NAVELBINE® 30mg : Vinorelbine (as tartrate) 30mg

ההתוויה הרשומה לתכשיר בישראל :

For the treatment of non small cell lung cancer.
For the treatment of advanced breast cancer.

מהות העדכונים:

עדכון עלון לרופא הכולל אזהרות ועדכוני נוסח בהתאם לעלון האסמכתא, תנאי הרישום ובהתאמה להנחיות משרד הבריאות.

להלן השינויים העיקריים בעלון לרופא:

Administration in patients with liver insufficiency

NAVELBINE can be administered at the standard dose of 60 mg/m²/week in patients with mild ~~liver impairment~~ hepatic disorder (bilirubin < 1.5 x ULN, and ALAT and/or ASAT ~~from~~between ~~–~~1.5 ~~to~~and 2.5 x ULN). In patients with moderate hepatic disorder ~~liver impairment~~ (bilirubin between~~from~~ 1.5 and~~to~~ 3 x ULN, independent~~whatever the levels~~ of ALAT and ASAT level), NAVELBINE needs to~~should~~ be administered at a dose of 50 mg/m²/week. ~~The a~~Administration of NAVELBINE ~~in~~to patients with severe hepatic disorder ~~impairment~~ is contra-indicated: (see sections 4.3, 4.4, 5.2).

[…]

Oral NAVELBINE ~~was~~ has been studied in patients with hepatic disorder~~liver impairment~~ at the following ~~doses~~dosages:

- 60 mg/m² in 7 patients with mild hepatic disorder~~liver impairment~~ (bilirubin < 1.5 x ULN, and ALAT and/or ASAT between~~from~~ 1.5 and~~to~~ 2.5 x ULN)~~;~~
- 50 mg/m² in 6 patients with moderate hepatic disorder ~~liver impairment~~ (bilirubin between~~from~~ 1.5 and~~to~~ 3 x ULN, ~~whatever the levels~~independent of ALAT and ASAT level).

The safety and pharmacokinetics of vinorelbine were not changed in these patients at the tested doses.

~~Total clearance of vinorelbine was neither modified between mild and moderate liver impairment nor was it altered in hepatically impaired patients when compared with clearance in patients with normal liver function~~.

Oral NAVELBINE has~~was~~ not been studied in patients with severe hepatic disorder~~impairment~~, therefore its use is contra-indicated in these patients: (see sections 4.2, 4.3, 5.2).

[…]

Women of child-bearing potential / contraception in males and females

Due to the genotoxic potential of vinorelbine (see section 5.3), ~~W~~women of child-bearing potential ~~must~~ should use effective contraception during ~~treatment~~ therapy with vinorelbine and for 7 months after treatment.

~~**Contraception in men**~~

Men ~~must~~ should use effective contraception during treatment with vinorelbine and for 4 months after treatment.

As vinorelbine is genotoxic, genetic counselling is also recommended for those wishing to conceive after therapy.

[…]

- **Special patient groups**

Renal and liver impairment:

The effects of renal dysfunction on the pharmacokinetics of vinorelbine have not been studied. However, dose reduction in case of reduced renal function is not indicated with vinorelbine due to the low level of renal elimination.

Pharmacokinetics of orally administered vinorelbine were not modified after administration of 60 mg/m² in 7 patients with mild hepatic disorder ~~liver impairment~~ (bilirubin < 1.5 x ULN, and AL~~A~~T and/or AS~~A~~T between~~from~~ 1.5 and~~to~~ 2.5 x ULN) and of 50 mg/m² in 6 patients with moderate hepatic disorder~~liver impairment~~ (bilirubin between~~from~~ 1.5 and~~to~~ 3 x ULN, independent~~whatever the levels~~ of AL~~A~~T and AS~~A~~T level). The safety and pharmacokinetics of vinorelbine were not changed in these patients at the tested doses. ~~Total clearance of vinorelbine was neither modified between mild and moderate impairment nor was it altered in hepatically impaired patients when compared with clearance in patients with normal liver function.~~

No data is available for patients with severe hepatic disorder~~liver impairment~~, therefore NAVELBINE is contra-indicated in these patients: (see sections 4.2, 4.3 and 4.4).

[…]

עלון לרופא המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://israeldrugs.health.gov.il/#!/byDrug

בברכה,

פאדאגיס ישראל סוכנויות בע"מ