

פברואר 2025
רופא/ה, רוקח/ת נכבד/ה,

הנדון: עדכון עלונים של נוביטרופן 5 מ"ג טבליות
NOVITROPAN 5 MG TABLETS

אנו מבקשים להודיעכם כי העלון לצרכן של התכשיר שבנדון עודכן בעקבות שינוי התוויה וקביעת משטר המיבון של התכשיר. בנוסף, ישנו עלון חדש לרופא.

הרכב וחוזק חומר פעיל:

OXYBUTYNIN HYDROCHLORIDE 5 MG

ההתוויה המאושרת:

Novitropan is indicated for the symptomatic treatment of urinary incontinence, urgency, and frequency in the unstable bladder, whether due to neurogenic bladder disorders (detrusor hyperreflexia) in conditions such as multiple sclerosis and spina bifida, or to idiopathic detrusor instability (motor urge incontinence).

Paediatric population

Novitropan is indicated in children of 5 years of age or older for:

- Urinary incontinence, urgency, and frequency in unstable bladder conditions due to idiopathic overactive bladder or neurogenic bladder disorders (detrusor overactivity).
- Nocturnal enuresis associated with detrusor overactivity, in conjunction with nondrug therapy, when other treatment has failed.

משטר המינון המאושר:

Posology

The dosage ~~and treatment regimen will be determined by the doctor only. The generally accepted dosage is:~~ should be determined individually.

Adults

~~One tablet 2-3 times per day. The maximum daily dosage is 4 tablets.~~

The usual dose is 5 mg two or three times a day. This may be increased to a maximum of 5 mg four times a day (maximum dose 20 mg oxybutynin hydrochloride per day) to obtain a clinical response provided that the side effects are tolerated.

Elderly

The elimination half-life is increased in the elderly. Therefore, a dose of 2.5 mg twice a day, particularly if the patient is frail, is likely to be adequate. This dose may be increased to 5 mg two times a day to obtain a clinical response provided the side effects are well tolerated.

Paediatric population

~~One tablet twice a day. The maximum daily dosage is 3 tablets.~~

Novitropan is not recommended in children under 5 years of age due to the absence of data.

Novitropan should be used in children 6 years of age and older due to potential swallowing difficulties and risk of choking in younger children.

For children under 6 years old, alternative treatments should be considered.

Neurogenic bladder instability: the usual dose is 2.5 mg twice a day. This dose may be increased to 5 mg two or three times a day to obtain a clinical response provided the side effects are well tolerated.

~~If Novitropan is intended for the treatment of night time bedwetting, the last dose should be taken before bedtime.~~

Nocturnal enuresis: the usual dose is 2.5 mg twice a day. This dose may be increased to 5 mg two or three times a day to obtain a clinical response provided the side effects are tolerated. The last dose should be given before bedtime.

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות
<http://www.health.gov.il>

ניתן לקבלם מודפסים על ידי פניה לחברת כצט בע"מ, רח' החרש 4 הוד השרון, 1-700-500-220

בברכה,

אלון אופיר

רוקח ממונה, כצט תעשיות כימיות בע"מ