

יולי 2024

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

הריני להודיעכם כי העלון לרופא של התכשיר עודכן:

SPINRAZA

ספינרזה

SOLUTION FOR INJECTION

מרכיב פעיל : NUSINERSEN

התוויות מאושרות :

Spinraza is indicated for the treatment of 5q Spinal Muscular Atrophy except type 0 and type IV.

להלן העדכונים בעלון לרופא המהווים החמרות -

4.4 Special warnings and precautions for use

Lumbar puncture procedure

There is a risk of adverse reactions occurring as part of the lumbar puncture procedure (e.g. arachnoiditis, headache, back pain, vomiting; see section 4.8). Potential difficulties with this route of administration may be seen in very young patients and those with scoliosis. The use of ultrasound or other imaging techniques to assist with intrathecal administration of Spinraza, can be considered at the physician's discretion. Should arachnoiditis be suspected, an MRI should be performed to confirm arachnoiditis and the extent of the inflammation. Identification of arachnoiditis precludes the use of the injection site until local inflammation has been ruled out.

Table 1: Adverse reactions related to Spinraza administration

MedDRA System Organ Class	Adverse reaction	Frequency category
Infections and infestations	Meningitis	Not known
Immune system disorders	Hypersensitivity**	Not known
Nervous system disorders	Headache*	Very common
	Aseptic meningitis	Not known
	<u>Arachnoiditis</u>	<u>Not known</u>
Gastrointestinal disorders	Vomiting*	Very common
Musculoskeletal and connective tissue disorders	Back pain*	Very common

*Adverse reactions considered related to the lumbar puncture procedure. These reactions can be considered manifestations of post-lumbar puncture syndrome. These adverse reactions were reported in CS4 (later onset SMA) with an incidence at least 5% higher in patients treated with Spinraza (n=84) compared to Sham control.

**e.g. angiodema, urticaria and rash.

העלון לרופא נמצא בקישור וכן הועבר לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה,
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