

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 -

Missed or delayed doses

~~If a loading dose is delayed or missed Spinraza should be administered as soon as possible, with at least 14 days between doses, and continue dosing at the prescribed frequency. If a maintenance dose is delayed or missed, Spinraza should be administered as soon as possible and dosing continued every 4 months.~~

If a loading or a maintenance dose is delayed or missed, Spinraza should be administered according to the schedule in Table 1 below.

Table 1: Recommendations for delayed or missed dose

<u>Delayed or missed dose</u>	<u>Timing of Dosing Administration</u>
<u>Loading dose</u>	
<ul style="list-style-type: none"> Administer the delayed or missed loading dose as soon as possible with at least 14 days between doses; continue with subsequent doses on the prescribed intervals from the last dose. <p>e.g. if the third loading dose is administered 30 days late at Day 58 (instead of the original schedule at Day 28), then the fourth loading dose should be administered 35 days later at Day 93 (instead of the original schedule at Day 63) with a maintenance dose 4 months thereafter.</p>	
<u>Maintenance dose</u>	<u>Timing of Dosing Administration</u>

<u>> 4 to < 8 months from last dose</u>	<ul style="list-style-type: none"> • <u>Administer the delayed maintenance dose as soon as possible; then</u> • <u>The next maintenance dose per the original scheduled date, as long as these two doses are administered at least 14 days apart*;</u>
<u>≥ 8 to < 16 months from last dose</u>	<ul style="list-style-type: none"> • <u>Administer the missed dose as soon as possible and then the next dose 14 days later*;</u>
<u>≥ 16 to < 40 months from last dose</u>	<ul style="list-style-type: none"> • <u>Administer the missed dose as soon as possible and then the next dose 14 days later, followed by a third dose 14 days later*;</u>
<u>≥ 40 months from last dose</u>	<ul style="list-style-type: none"> • <u>Administer the entire loading regimen on the prescribed intervals (Days 0, 14, 28 and 63)*;</u>
<u>*then subsequently to the above recommendations, a maintenance dose 4 months after the last dose should be administered and repeated every 4 months.</u>	

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

בברכה,
מדיסון פארמה בע"מ