

PICTURE YOUR

ONE DOSE LIFE

A guide to starting a conversation about ITVISMA

Lab tests and administration of oral corticosteroids are required before and after injection.

Scarlette R., 17 years old
Student
Living with SMA

Scarlette hasn't received ITVISMA. Individuals shown were compensated for their time.

A personalized guide for talking to your doctor about spinal muscular atrophy (SMA) and treatment with ITVISMA

ITVISMA is the only one-time gene replacement therapy for kids 2 years of age and older, teens, and adults with SMA

What is ITVISMA?

ITVISMA is a prescription gene therapy used to treat adults and children 2 years of age and older with spinal muscular atrophy (SMA). ITVISMA is given as a one-time intrathecal injection.

What is the most important safety information I should know about ITVISMA?

- ITVISMA can increase liver enzyme levels and cause hepatotoxicity.
- Patients will receive an oral corticosteroid medication before and after ITVISMA injection and will undergo regular blood tests to monitor liver function.
- Patients and caregivers should contact the patient's doctor immediately if the patient's skin and/or whites of the eyes become yellowish, if the patient misses a dose of corticosteroid or vomits it up, or if the patient experiences a decrease in alertness.

Please see additional Important Safety Information on [page 5](#) and [Full Prescribing Information](#).

 **itvisma**[®]
(onasemnogene abeparvovec-brve)
suspension for intrathecal injection

SECTION 1

BEFORE YOUR APPOINTMENT

Take note of how you're feeling today and any changes you've noticed over the last few months. This is also a good time to think about your current spinal muscular atrophy (SMA) treatment. Sharing this information with your doctor will help you have a more candid conversation with them.

1 What's your current level of mobility? Select all that apply.

"Assistance" here refers to any person, tool, or aid that helps to accomplish the given task.



I can walk
(independently or
with assistance)



I can stand
(independently or
with assistance)



I'm in a wheelchair
(part-time
or full-time)



I can sit upright
(independently or
with assistance)



I can lie down
(independently or
with assistance)

2 How would you describe your motor function and/or physical ability over the last 6 months?

It's improving

It's stayed the same

It's getting worse

I'm not sure

What, if anything, did you notice that stands out to you?

3 Have you noticed a change in any of the following activities in the last 6 months? Select all that apply.

Walking

Sitting

Standing

Eating

Using buttons/zippers

Brushing my teeth

Talking

Swallowing

Using the bathroom

Transferring seats

Pushing and/or
pulling objects

None

Other:

4 When I think about my current SMA treatment, I feel: (Select all that apply.)



Very
satisfied



Somewhat
satisfied



Neutral



Somewhat
unsatisfied



Very
unsatisfied

5 Is there anything you want to share about your current dosing schedule? If yes, please describe. (eg, traveling for treatment, refills, injections, insurance authorizations, etc)

What should I watch for before and after injection with ITVISMA?

- Infections before or after ITVISMA injection can lead to more serious complications. Patients, caregivers, and close contacts of the patient should follow infection prevention procedures. Patients and caregivers should contact the patient's doctor immediately if the patient experiences any signs of a possible infection such as coughing, wheezing, sneezing, runny nose, sore throat, or fever.

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SECTION 2

DURING YOUR APPOINTMENT

Consider bringing a friend or loved one with you to your appointment, so you can take notes and ask questions together.

Be sure to share the highlights from your pre-appointment prep in Section 1, then use the questions below to explore your options with your doctor.

Let's learn more about one-time ITVISMA

- How is ITVISMA different from my previous/current spinal muscular atrophy (SMA) treatment(s)?
- How is ITVISMA administered? What is the procedure like?
- How do I know if I'm eligible for treatment?
- What results can I expect with ITVISMA?
- How will we track my progress?
- If I receive treatment, will I need to stop or adjust any of my current medications, therapies, or devices?
- What potential side effects might I experience?
- Will I need special monitoring or follow-up visits after I receive treatment?

Use the space below to capture any additional questions or notes.



Connect with the Novartis Patient Support™ team to learn how they can help with insurance.

Can a one-time SMA treatment be right for you? Talk to a doctor.

What should I watch for before and after injection with ITVISMA? (cont)

- Decreased platelet counts could occur following injection with ITVISMA. Seek immediate medical attention if the patient experiences unexpected bleeding or bruising.
- Peripheral sensory neuropathy has occurred with ITVISMA administration. Patients and caregivers should contact the patient's doctor right away if the patient experiences numbness, tingling, prickling, or pain in the arms, hands, legs, and/or feet.

Please see the **Indication and additional Important Safety Information** on [page 5](#) and [Full Prescribing Information](#).

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SECTION 3

AFTER YOUR APPOINTMENT



Learn more about ITVISMA

If your doctor has determined that ITVISMA is right for you, learn about the study results, safety information, financial assistance, and more by scanning the QR code or visit ITVISMA.com.

Follow-up questions for your doctor and larger health care team? Jot down any thoughts about your next steps here!

“A fundamental part of having SMA is communicating with your doctors and having open conversations with them.”

– Scarlette R.

Scarlette lives with SMA and hasn't received ITVISMA. She was compensated for her time.



Start a conversation about a one-dose treatment

SMA, spinal muscular atrophy.

What should I watch for before and after injection with ITVISMA? (cont)

- Decreased blood platelet and red blood cell counts, sudden kidney change, and increased bruising or bleeding, which could be signs of thrombotic microangiopathy (TMA), can occur. Patients and caregivers should seek immediate medical attention if the patient experiences unexpected bruising or bleeding, seizures, or decreased urine output.
- There is a theoretical risk of tumor development with gene therapies such as ITVISMA. Patients and caregivers should contact the patient's doctor and Novartis Gene Therapies, Inc. at 1-833-828-3947 if a tumor develops.



Please see the Indication and additional Important Safety Information on [page 5](#) and [Full Prescribing Information](#).

INDICATION AND IMPORTANT SAFETY INFORMATION

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- There is a theoretical risk of tumor development with gene therapies such as ITVISMA. Patients and caregivers should contact the patient's doctor and Novartis Gene Therapies, Inc. at 1-833-828-3947 if a tumor develops.

What do I need to know about vaccinations and ITVISMA?

- Patients and caregivers should consult the patient's doctor about vaccinations and ITVISMA.
- Patients and caregivers should talk with the patient's doctor to determine if adjustments to the patient's vaccination schedule are necessary during corticosteroid use.
- Protection against influenza and respiratory syncytial virus (RSV) is recommended, and vaccination status should be up-to-date prior to ITVISMA administration.

What do I need to know about contraception and egg or sperm donation and ITVISMA?

- Women of childbearing potential should use an effective method of contraception and refrain from egg donation for 6 months following ITVISMA injection.
- Men capable of fathering a child should use a barrier method of contraception and refrain from sperm donation for 3 months following ITVISMA injection.

What are the possible or likely side effects of ITVISMA?

- The most common adverse reactions that occurred in patients treated with ITVISMA were upper respiratory tract infection, fever, upper gastrointestinal symptoms, increased liver enzymes, headache, dizziness, pain in extremity, low platelet counts, and sensory disturbance.

The safety information provided here is not comprehensive. Talk to the patient's doctor about any side effects that bother the patient or that don't go away. You are encouraged to report suspected side effects by contacting the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch, or Novartis Gene Therapies, Inc. at 1-833-828-3947.

Please see the [Full Prescribing Information](#).



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