

MEDICATION GUIDE
IMULDOSA (im ul doe' sah)
(ustekinumab-srlf)

injection, for subcutaneous or intravenous use

What is the most important information I should know about IMULDOSA?

IMULDOSA is a medicine that affects your immune system. IMULDOSA can increase your risk of having serious side effects, including:

Serious infections. IMULDOSA may lower the ability of your immune system to fight infections and may increase your risk of infections. Some people have serious infections while taking ustekinumab products, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses. Some people have to be hospitalized for treatment of their infection.

- Your doctor should check you for TB before starting IMULDOSA.
- If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with IMULDOSA and during treatment with IMULDOSA.
- Your doctor should watch you closely for signs and symptoms of TB while you are being treated with IMULDOSA.

You should not start taking IMULDOSA if you have any kind of infection unless your doctor says it is okay.

Before starting IMULDOSA, tell your doctor if you:

- think you have an infection or have symptoms of an infection such as:
 - fever, sweat, or chills
 - muscle aches
 - cough
 - shortness of breath
 - blood in phlegm
 - weight loss
 - warm, red, or painful skin or sores on your body
 - diarrhea or stomach pain
 - burning when you urinate or urinate more often than normal
 - feel very tired
- are being treated for an infection or have any open cuts.
- get a lot of infections or have infections that keep coming back.
- have TB, or have been in close contact with someone with TB.

After starting IMULDOSA, call your doctor right away if you have any symptoms of an infection (see above). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. IMULDOSA can make you more likely to get infections or make an infection that you have worse.

People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections. These infections can spread throughout the body and cause death. People who take IMULDOSA may also be more likely to get these infections.

Cancers. IMULDOSA may decrease the activity of your immune system and increase your risk for certain types of cancers. Tell your doctor if you have ever had any type of cancer. Some people who are receiving ustekinumab products and have risk factors for skin cancer have developed certain types of skin cancers. During your treatment with IMULDOSA, tell your doctor if you develop any new skin growths.

Posterior Reversible Encephalopathy Syndrome (PRES). PRES is a rare condition that affects the brain and can cause death. The cause of PRES is not known. If PRES is found early and treated, most people recover. Tell your doctor right away if you have any new or worsening medical problems including:

- headache
- seizures
- confusion
- vision problems

What is IMULDOSA?

IMULDOSA is a prescription medicine used to treat:

- adults and children 6 years and older with moderate or severe psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults and children 6 years and older with active psoriatic arthritis.
- adults 18 years and older with moderately to severely active Crohn's disease.
- adults 18 years and older with moderately to severely active ulcerative colitis.

It is not known if IMULDOSA is safe and effective in children less than 6 years of age.

Do not take IMULDOSA if you are allergic to ustekinumab products or any of the ingredients in IMULDOSA. See the end of this Medication Guide for a complete list of ingredients in IMULDOSA.

Before you receive IMULDOSA, tell your doctor about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section **“What is the most important information I should know about IMULDOSA?”**
- ever had an allergic reaction to ustekinumab products. Ask your doctor if you are not sure.
- have recently received or are scheduled to receive an immunization (vaccine). People who take IMULDOSA

should not receive live vaccines. Tell your doctor if anyone in your house needs a live vaccine. The viruses used in some types of live vaccines can spread to people with a weakened immune system and can cause serious problems. **You should not receive the BCG vaccine during the one year before receiving IMULDOSA or one year after you stop receiving IMULDOSA.**

- have any new or changing lesions within psoriasis areas or on normal skin.
- are receiving or have received allergy shots, especially for serious allergic reactions. Allergy shots may not work as well for you during treatment with IMULDOSA. IMULDOSA may also increase your risk of having an allergic reaction to an allergy shot.
- receive or have received phototherapy for your psoriasis.
- are pregnant or plan to become pregnant. It is not known if IMULDOSA can harm your unborn baby. You and your doctor should decide if you will receive IMULDOSA. See “What should I avoid while using IMULDOSA?”
- received IMULDOSA while you were pregnant. It is important that you tell your baby’s healthcare provider before any vaccinations are given to your baby.
- are breastfeeding or plan to breastfeed. IMULDOSA can pass into your breast milk.
- Talk to your doctor about the best way to feed your baby if you receive IMULDOSA.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use IMULDOSA?

- Use IMULDOSA exactly as your doctor tells you to.
- Adults with Crohn’s disease and ulcerative colitis will receive the first dose of IMULDOSA through a vein in the arm (intravenous infusion) in a healthcare facility by a healthcare provider. It takes at least 1 hour to receive the full dose of medicine. You will then receive IMULDOSA as an injection under the skin (subcutaneous injection) 8 weeks after the first dose of IMULDOSA, as described below.
- Adults with psoriasis or psoriatic arthritis, and children 6 years and older with psoriasis or psoriatic arthritis will receive IMULDOSA as an injection under the skin (subcutaneous injection) as described below.
- **Injecting IMULDOSA under your skin**
 - IMULDOSA is intended for use under the guidance and supervision of your doctor. In children 6 years and older, it is recommended that IMULDOSA be administered by a healthcare provider. If your doctor decides that you or a caregiver may give your injections of IMULDOSA at home, you should receive training on the right way to prepare and inject IMULDOSA. Your doctor will determine the right dose of IMULDOSA for you, the amount for each injection, and how often you should receive it. Do not try to inject IMULDOSA yourself until you or your caregiver have been shown how to inject IMULDOSA by your doctor or nurse.
 - Inject IMULDOSA under the skin (subcutaneous injection) in your upper arms, buttocks, upper legs (thighs) or stomach area (abdomen).
 - Do not give an injection in an area of the skin that is tender, bruised, red or hard.
 - Use a different injection site each time you use IMULDOSA.
 - If you inject more IMULDOSA than prescribed, call your doctor right away.
 - Be sure to keep all of your scheduled follow-up appointments.

Read the detailed Instructions for Use at the end of this Medication Guide for instructions about how to prepare and inject a dose of IMULDOSA, and how to properly throw away (dispose of) used needles and syringes. The syringe, needle and vial must never be re-used. After the rubber stopper is punctured, IMULDOSA can become contaminated by harmful bacteria which could cause an infection if re-used. Therefore, throw away any unused portion of IMULDOSA.

What should I avoid while using IMULDOSA?

You should not receive a live vaccine while taking IMULDOSA. See “**Before you receive IMULDOSA, tell your doctor about all of your medical conditions, including if you:**”

What are the possible side effects of IMULDOSA?

IMULDOSA may cause serious side effects, including:

- See “**What is the most important information I should know about IMULDOSA?**”
- **Serious allergic reactions.** Serious allergic reactions can occur with IMULDOSA. Stop using IMULDOSA and get medical help right away if you have any of the following symptoms of a serious allergic reaction:
 - feeling faint
 - chest tightness
 - swelling of your face, eyelids, tongue, or throat
 - skin rash
- **Lung inflammation.** Cases of lung inflammation have happened in some people who receive ustekinumab products and may be serious. These lung problems may need to be treated in a hospital. Tell your doctor right

away if you develop shortness of breath or a cough that doesn't go away during treatment with IMULDOSA.

Common side effects of IMULDOSA include:

- nasal congestion, sore throat, and runny nose
- upper respiratory infections
- fever
- headache
- tiredness
- itching
- nausea and vomiting
- redness at the injection site
- vaginal yeast infections
- urinary tract infections
- sinus infection
- bronchitis
- diarrhea
- stomach pain

These are not all of the possible side effects of IMULDOSA. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Accord BioPharma, Inc. at 1-866-941-7875.

How should I store IMULDOSA?

- Store IMULDOSA vials and prefilled syringes in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Store IMULDOSA vials standing up straight.
- Store IMULDOSA in the original carton to protect it from light until time to use it.
- Do not freeze IMULDOSA.
- Do not shake IMULDOSA.

If needed, individual IMULDOSA prefilled syringes may also be stored at room temperature up to 86°F (30°C) for a maximum single period of up to 30 days in the original carton to protect from light. Record the date when the prefilled syringe is first removed from the refrigerator on the carton in the space provided. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage. Do not use IMULDOSA after the expiration date on the carton or on the prefilled syringe.

Keep IMULDOSA and all medicines out of the reach of children.

General information about the safe and effective use of IMULDOSA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use IMULDOSA for a condition for which it was not prescribed. Do not give IMULDOSA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about IMULDOSA that was written for health professionals.

What are the ingredients in IMULDOSA?

Active ingredient: ustekinumab-srlf

Inactive ingredients: **Single-dose prefilled syringe for subcutaneous use** contains histidine, L-histidine hydrochloride monohydrate, polysorbate 80, and sucrose. **Single-dose vial for intravenous infusion** contains edetate disodium, histidine, L-histidine hydrochloride monohydrate, methionine, polysorbate 80, and sucrose.

Manufactured by: Accord BioPharma Inc. 8041 Arco Corporate Drive, Suite 200, Raleigh, North Carolina (NC), 27617 USA.

US License No. 2105

For more information go to www.imuldosa.com or call 1-866-941-7875.

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INSTRUCTIONS FOR USE
IMULDOSA [im ul doe' sah]
(ustekinumab-srlf)
injection, for subcutaneous use

Instructions for injecting IMULDOSA using a prefilled syringe.

Read this Instructions for Use before you start using IMULDOSA. Your doctor or nurse should show you how to prepare and give your injection of IMULDOSA the right way.

If you cannot give yourself the injection:

- ask your doctor or nurse to help you, or
- ask someone who has been trained by a doctor or nurse to give your injections.

Do not try to inject IMULDOSA yourself until you have been shown how to inject IMULDOSA by your doctor, nurse or health professional.

Important information:

- Before you start, check the carton to make sure that it is the right dose. You will have either 45 mg or 90 mg as prescribed by your doctor.
 - If your dose is 45 mg, you will receive one 45 mg prefilled syringe.
 - If your dose is 90 mg, you will receive either one 90 mg prefilled syringe or two 45 mg prefilled syringes.
If you receive two 45 mg prefilled syringes for a 90 mg dose, you will need to give yourself two injections, one right after the other.
- Children 12 years of age and older with psoriasis who weigh 132 pounds or more may use a prefilled syringe.
- **Store IMULDOSA** in a refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light.
- If needed, individual IMULDOSA prefilled syringes may be stored at room temperature up to 86°F (30°C) for a maximum period of up to 30 days in the original carton to protect from light. Record the date when the prefilled syringe is first removed from the refrigerator on the carton in the space provided. If a syringe has been stored at room temperature, it should not be returned to the refrigerator.
- Check the expiration date on the prefilled syringe and carton. If the expiration date has passed or if the prefilled syringe has been kept at room temperature up to 86°F (30°C) for longer than a maximum single period of 30 days or if the prefilled syringe has been stored above 86°F (30°C), do not use it. If the expiration date has passed or if the prefilled syringe has been stored above 86°F (30°C), call your doctor or pharmacist, or call 1-866-941-7875 for help.
- Make sure the syringe is not damaged.
- Check your prefilled syringe for any particles or discoloration. Your prefilled syringe should look clear to slightly clear and colorless to slightly yellow solution.
- Do not use if it is frozen, discolored, cloudy or has particles. Get a new prefilled syringe.
- **Do not shake the prefilled syringe at any time.** Shaking your prefilled syringe may damage your IMULDOSA medicine. If your prefilled syringe has been shaken, do not use it. Get a new prefilled syringe.
- To reduce the risk of accidental needle sticks, each prefilled syringe has a needle guard that is automatically activated to cover the needle after you have given your injection. Do not pull back on the plunger at any time.

Gather the supplies you will need to prepare IMULDOSA and to give your injection. (See Figure A)

You will need:

- antiseptic wipes
- cotton balls or gauze pads
- adhesive bandage
- your prescribed dose of IMULDOSA (See Figure B)
- FDA-cleared sharps disposal container. See “Step 4: Dispose of the syringe.”

Figure A

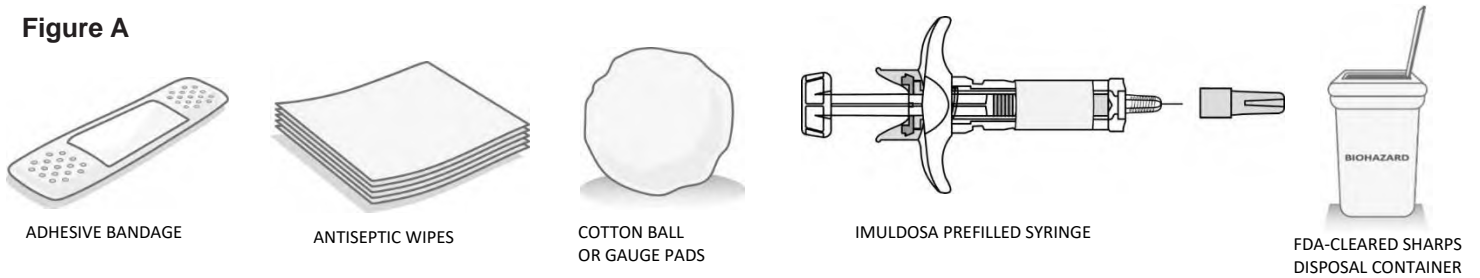
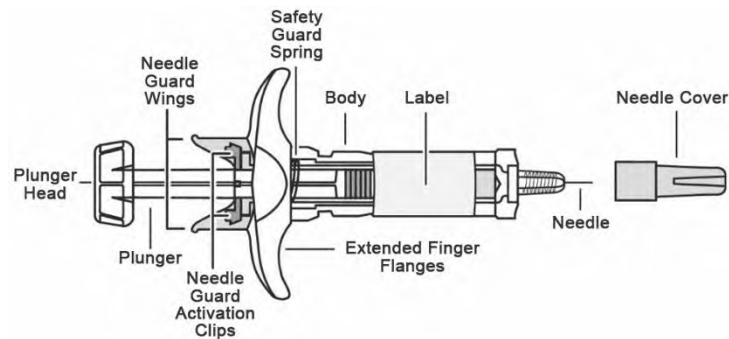


Figure B

To prevent premature activation of the needle safety guard, do not touch the needle guard activation clips at any time during use.



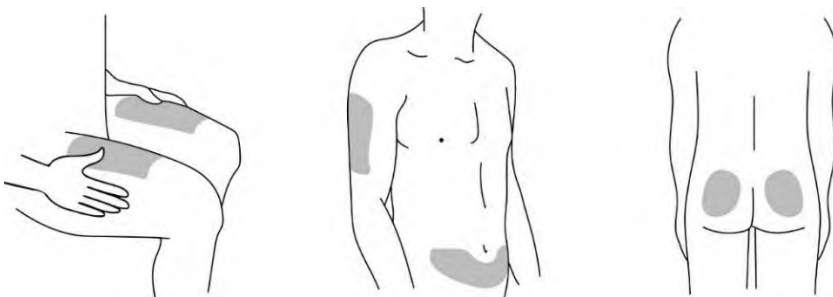
Step 1: Prepare the injection.

- Choose a well-lit, clean, flat work surface.
- Wash your hands well with soap and warm water.
- Hold the prefilled syringe with the covered needle pointing upward.

Step 2: Prepare your injection site

- Choose an injection site around your stomach area (abdomen), buttocks, upper legs (thighs). If a caregiver is giving you the injection, the outer area of the upper arms may also be used. **(See Figure C)**
- **Use a different injection site for each injection. Do not** give an injection in an area of the skin that is tender, bruised, red or hard.
- Clean the skin with an antiseptic wipe where you plan to give your injection.
- **Do not** touch this area again before giving the injection. Let your skin dry before injecting.
- **Do not** fan or blow on the clean area.

Figure C

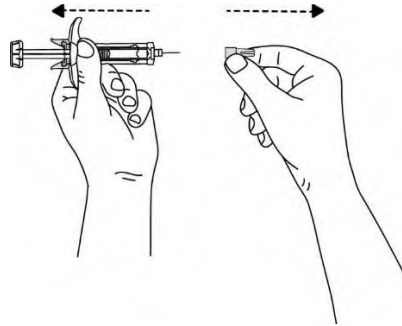


*Areas in gray are recommended injection sites.

Step 3: Inject IMULDOSA

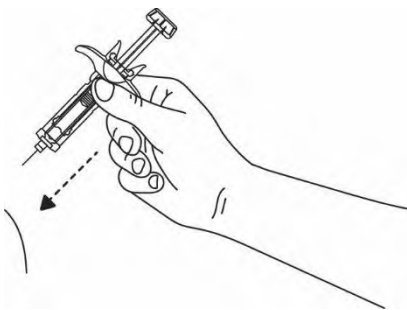
- Remove the needle cover when you are ready to inject your IMULDOSA.
- **Do not** touch the plunger or the plunger head while removing the needle cover.
- Hold the body of the prefilled syringe with one hand and pull the needle cover straight off. **(See Figure D)**
- Put the needle cover in the trash.
- You may also see a drop of liquid at the end of the needle. This is normal.
- **Do not** touch the needle or let it touch anything.
- **Do not** use the prefilled syringe if it is dropped without the needle cover in place. Call your doctor, nurse or health professional for instructions.

Figure D



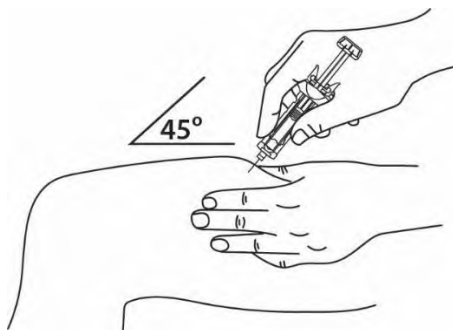
- Hold the body of the prefilled syringe in one hand between the thumb and index fingers. **(See Figure E)**

Figure E



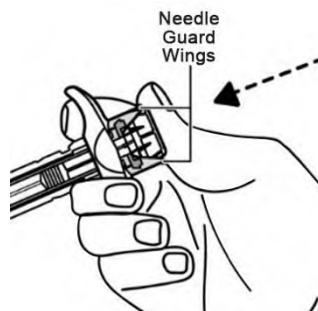
- **Do not** pull back on the plunger at any time.
- Use the other hand to gently pinch the cleaned area of skin. Hold firmly.
- Use a quick, dart-like motion to insert the needle into the pinched skin at about a 45-degree angle. **(See Figure F)**

Figure F



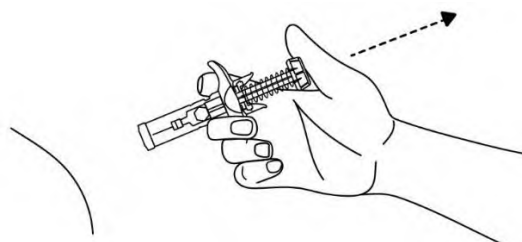
- Inject all of the liquid by using your thumb to push in the plunger until the plunger head is completely between the needle guard wings. **(See Figure G)**

Figure G



- When the plunger is pushed as far as it will go, keep pressure on the plunger head. Take the needle out of the skin and let go of the skin.
- Slowly take your thumb off the plunger head. This will let the empty syringe move up until the entire needle is covered by the needle guard. **(See Figure H)**

Figure H



- When the needle is pulled out of your skin, there may be a little bleeding at the injection site. This is normal. You can press a cotton ball or gauze pad to the injection site if needed. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

If your dose is 90 mg, you will receive either one 90 mg prefilled syringe or two 45 mg prefilled syringes. If you receive two 45 mg prefilled syringes for a 90 mg dose, you will need to give yourself a second injection right after the first. Repeat Steps 1 to 3 for the second injection using a new syringe. Choose a different site for the second injection.

Step 4: Dispose of the syringe.

- Put the syringe in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose syringes in your household trash.**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of heavy-duty plastic.
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out.
 - upright and stable during use,
 - leak-resistant,
 - and properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local or state laws about how to throw away syringes and needles. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- Do not dispose of your sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your sharps disposal container.
- If you have any questions, talk to your doctor or pharmacist.

Keep IMULDOSA and all medicines out of the reach of children.

Manufactured by:

Accord BioPharma Inc. 8041 Arco Corporate Drive, Suite 200, Raleigh, North Carolina (NC), 27617 USA
US License No. 2105

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