



TIME TO TALK IMMUNO-ONCOLOGY™



Bristol-Myers Squibb

REGENERON | SANOFI GENZYME

IMMUNE CHECKPOINT INHIBITORS

SIDE EFFECTS OF IMMUNE CHECKPOINT INHIBITORS

Because immune checkpoint inhibitors (or immunotherapy) work to increase the ability of your own immune system to kill cancer cells, the side effects are different from those that may happen with chemotherapy drugs. Immunotherapy generally does not cause significant nausea or affect blood cell counts as sometimes happens with chemotherapy medications.

After the infusion of the immunotherapy drug, you may feel a little tired or achy for the next few days as your immune system starts to ramp up its attack on the cancer cells.

Sometimes the immunotherapy drug can cause the immune system to get overexcited. In these rare cases, immune cells can start to attack a normal part of your body rather than focusing on the cancer. This attack causes *auto-immune side effects*. If they are left untreated, the immune system can damage important organs and tissues in the body.

Because your immune system is present throughout your body, auto-immune side effects from immunotherapy can affect many parts of your body (**Figure 1**). Auto-immune side effects can happen even in areas where no cancer is present.

Auto-immune side effects can occur at any time during your treatment, even after you have been taking the cancer drug for months or years. It is important to pay close attention to your body to make sure you are not having any new, unexplained symptoms or symptoms that are getting worse. **Table 1** lists some symptoms you may notice in different parts of your body and when during treatment they may be more likely to occur.

Symptom Tracking

You may want to schedule a time each week to ask yourself whether you have noticed any new symptoms. Write them down so you can tell your healthcare provider about them. You can use this list of questions:

- How is my energy level?
- Do I have a new cough? Is my breathing the same as it was before I started taking the immunotherapy drug?
- Are my bowel movements normal (for me), or have I seen any changes?
- Do I have any new rashes on my body?
- Do I have pain anywhere that is not normal for me?

If you are having any new symptoms that bother you a lot or seem serious, always contact your healthcare team.

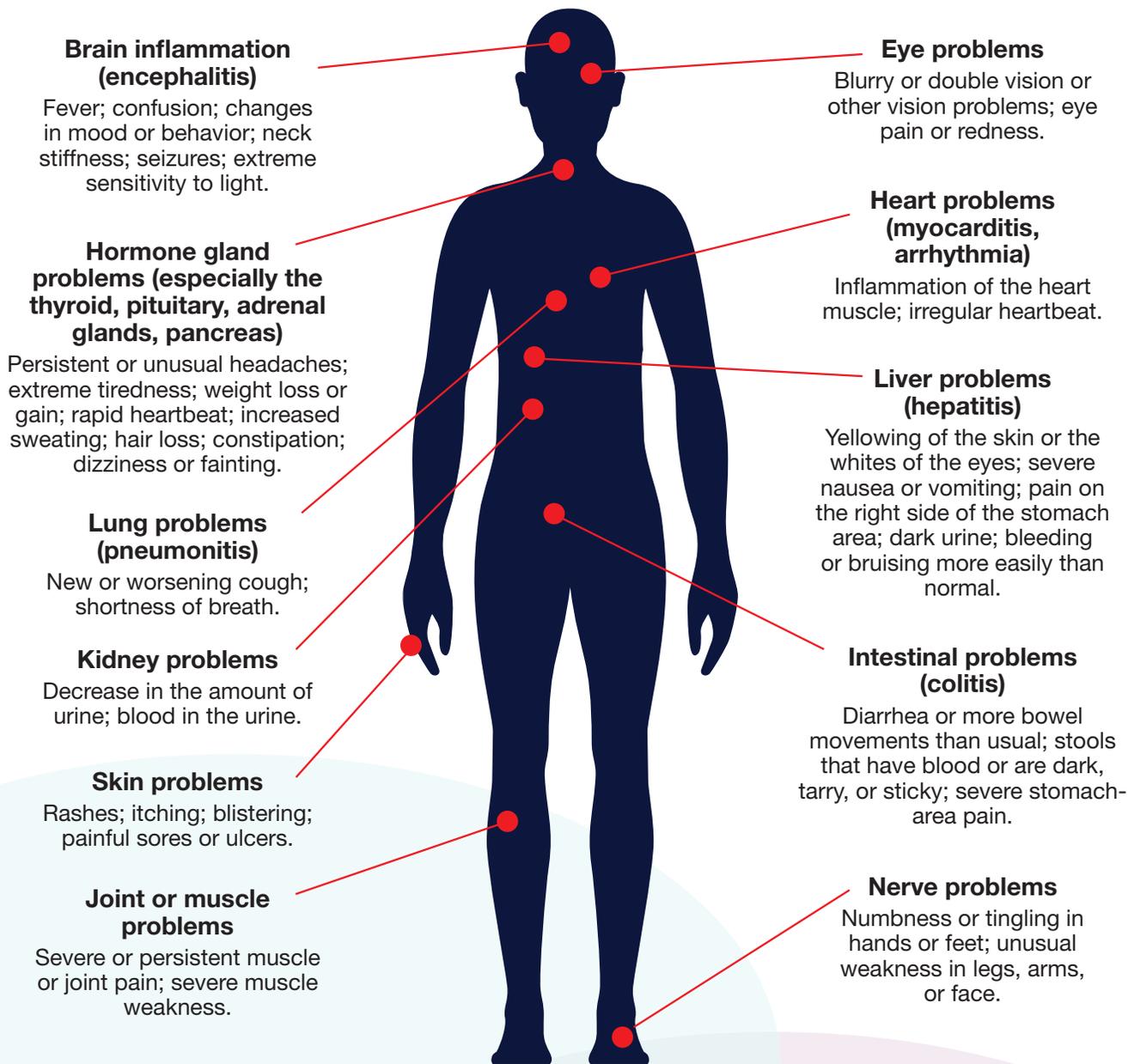


Figure 1. Auto-immune side effects may affect many parts of the body.

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Table 1. Symptoms of Possible Side Effects from Immunotherapy

	Part of Body Affected by Side Effect	When the Side Effect May Start to Occur	What You May Feel or See
More common symptoms	Gastrointestinal (GI) tract Most commonly occurs in the colon	Early in treatment (after 1 dose)	Diarrhea Blood in your stools or dark, tarry stools Severe abdominal pain or cramping Nausea or vomiting
	Skin Can happen anywhere on the body	Early in treatment (after 1 dose)	Rash Itching Lightening of skin Blisters or ulcers
	Hormone glands Most common in thyroid and pituitary glands	Mid-treatment (after 2 doses)	Excessive sleepiness Weight gain or weight loss Changes in mood or behavior Hair loss Feeling cold Constipation Excessive thirst or increased urination
Less common symptoms	Lungs	Mid-treatment (after 2 doses)	Shortness of breath New or worsening cough Chest pain
	Liver	Mid-treatment (after 2 doses)	Yellowing skin or eyes Dark urine Right-sided stomach pain
	Muscles and nerves Any muscle or nerve can be affected.	Late in treatment (after 3 or more doses)	Muscles: general weakness or fatigue Nerves: numbness or tingling
	Kidneys	Late in treatment (after 3 or more doses)	Decreased urination or dark urine Pain in the middle of the back Swelling in the ankles
	Brain and eyes	Late in treatment (after 3 or more doses)	Headache Confusion Changes in vision Excessive sleepiness or fatigue
	Heart	Late in treatment (after 3 or more doses)	Swelling in the ankles Chest pain Shortness of breath or difficulty breathing

Management of Side Effects

These side effects can generally be treated with drugs, such as corticosteroids, that calm down the overexcited immune system.

If you are having a side effect from immunotherapy, **it is very important to receive treatment with immune-suppressing drugs as soon as possible** to prevent severe or permanent damage to organs and tissues.

You should call your healthcare team to report any new or worsening symptom, large or small, so they can help you determine whether treatment for an autoimmune side effect is needed.

Side effects are treated differently depending on how severe they are. Some side effects can be managed during a clinic visit with your healthcare team. More serious side effects may require that you go to the hospital.

Figure 2 shows the way that treatment may change as the side effects become more serious.

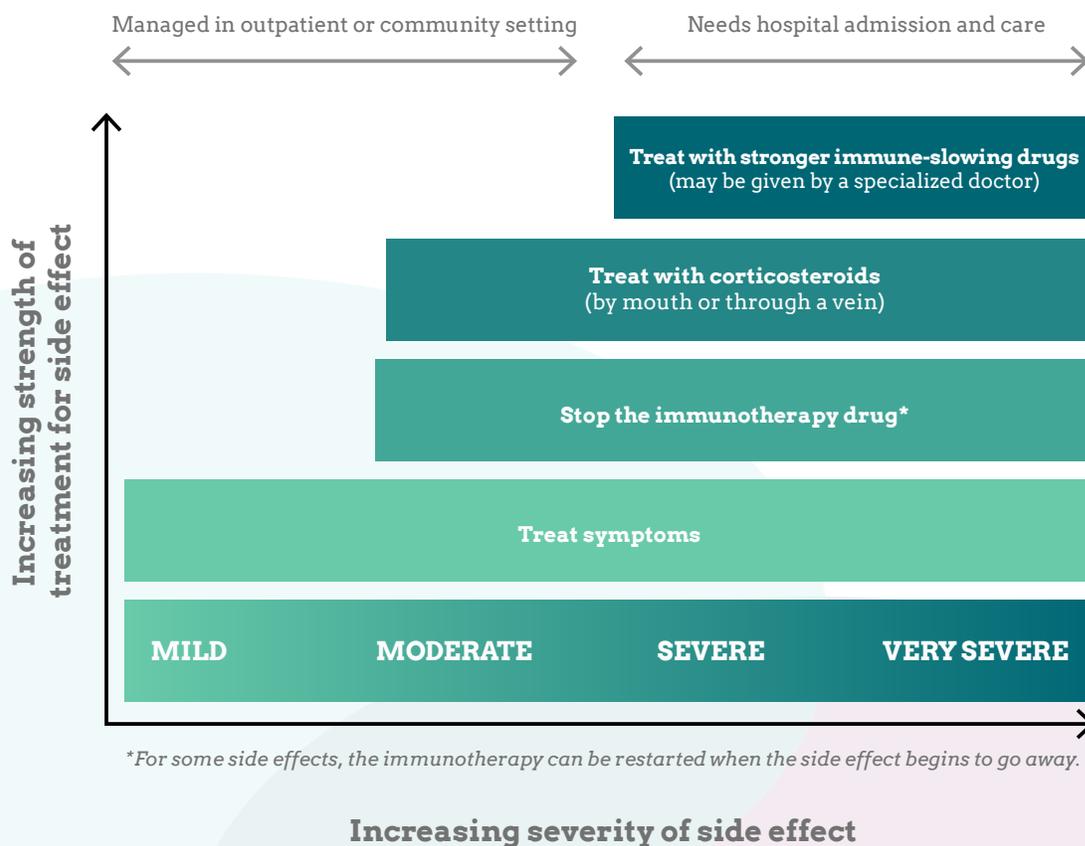


Figure 2. Changes in treatment depend on how severe the side effects are.

If you have an auto-immune side effect, the following steps may be taken:

- You may be given treatments that control your symptoms without interfering with the immune system.
Examples:
 - creams to soothe an itchy rash
 - medicines to lessen diarrhea
 - medicines that bring your hormone levels back to normal
- Treatment with the immunotherapy drug may be stopped for a short time, or completely.
- You may be treated with corticosteroids (for example, prednisone, dexamethasone, or methylprednisolone) to slow down the immune system. These can be given in creams (such as for a rash), taken as pills by mouth, or given through the vein.
- You may be treated with other immune-suppressing drugs. If additional immune-suppressing drugs are needed, your healthcare team may suggest that you visit a specialist who can help decide on the best medicine for you.

Self-Care

It is very important that you take care of yourself while you are receiving immunotherapy. Here are some tips:

- Eat a healthy, well-balanced diet.
- Exercise frequently, as approved by your doctor.
- Choose a family member or friend to be your caregiver at home. Talk with this person about your symptoms, feelings, and any concerns you have about your treatment. Don't be afraid to ask for help if you need it. Your caregiver can help you feel supported when you have concerns to discuss with the healthcare team.
- Talk to your healthcare team about any new symptoms, large or small. Don't wait until your next appointment if you notice that you are having a new symptom, even if you aren't sure that it was caused by the immunotherapy drug.

Don't wait! Remember that treating auto-immune side effects *early* will help prevent them from becoming more serious.