

MEDICATION GUIDE
INCIVEK (in-SEE-veck)
(telaprevir)
Tablets

Read this Medication Guide before you start taking INCIVEK® and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

INCIVEK is taken along with peginterferon alfa and ribavirin. You should also read those Medication Guides.

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

INCIVEK combination treatment may cause serious side effects including:

1. Skin rash and serious skin reactions. Skin rashes are common with INCIVEK combination treatment. Sometimes these skin rashes and other skin reactions can become serious, require treatment in a hospital, and may lead to death.

- **Call your healthcare provider right away if you develop any skin changes or itching during treatment with INCIVEK.**
- Your healthcare provider will decide if your skin changes or any of the following symptoms may be a sign of a serious skin reaction:
 - skin rash, with or without itching
 - fever
 - swelling of your face
 - blisters or skin lesions
 - mouth sores or ulcers
 - red or inflamed eyes, like “pink eye” (conjunctivitis)
- Your healthcare provider will decide if you need treatment for your skin rash or if you need to stop taking INCIVEK, or any of your other medicines.
- Never stop taking INCIVEK combination treatment without talking with your healthcare provider first.

See **“What are the possible side effects of INCIVEK?”** for more information about side effects.

2. Low red blood cell count (anemia), which can be severe. Tell your healthcare provider if you have any of these symptoms of anemia:

- dizziness
- tiredness
- shortness of breath
- weakness

Your healthcare provider will do blood tests regularly to check your red blood cell count during treatment. If your anemia is severe, your healthcare provider may tell you to stop taking INCIVEK. If INCIVEK is stopped for this reason, **do not** start taking it again.

3. Birth defects or death of your unborn baby. INCIVEK in combination with peginterferon alfa and ribavirin may cause birth defects or death of your unborn baby. If you are pregnant or your sexual partner is pregnant or plans to become pregnant, do not take these medicines. You or your sexual partner should not become pregnant while

taking INCIVEK with peginterferon alfa and ribavirin and for 6 months after treatment is over.

If you are a female who can become pregnant, or you are a female whose male partner takes these medicines:

- You must have a negative pregnancy test before starting treatment, each month during treatment, and for 6 months after your treatment ends.
- **You must use 2 forms of effective birth control during treatment and for the 6 months after treatment with these medicines.** Hormonal forms of birth control including birth control pills, vaginal rings, implants, or injections may not work during treatment with INCIVEK. You could become pregnant. Talk to your healthcare provider about other forms of birth control that may be used during this time. If your healthcare provider tells you to stop taking INCIVEK, peginterferon alfa and ribavirin, **you must still use 2 forms of birth control for the 6 months after treatment with these medicines. You may use a hormonal form of birth control as one of your 2 forms of birth control after 2 weeks of stopping INCIVEK.**
- If you or your female sexual partner becomes pregnant while taking INCIVEK, peginterferon alfa, and ribavirin or within 6 months after you stop taking these medicines, tell your healthcare provider right away. You or your healthcare provider should contact the Ribavirin Pregnancy Registry by calling 1-800-593-2214. The Ribavirin Pregnancy Registry collects information about what happens to mothers and their babies if the mother takes ribavirin while she is pregnant.

4. Do not take INCIVEK alone to treat chronic hepatitis C infection. INCIVEK must be used with peginterferon alfa and ribavirin to treat chronic hepatitis C infection.

What is INCIVEK?

INCIVEK is a prescription medicine used with the medicines peginterferon alfa and ribavirin to treat chronic (lasting a long time) hepatitis C genotype 1 infection in adults with stable liver problems, who have not been treated before or who have failed previous treatment.

It is not known if INCIVEK is safe and effective in children under 18 years of age.

Who should not take INCIVEK?

Do not take INCIVEK if you:

- are pregnant or may become pregnant. See **"What is the most important information I should know about INCIVEK?"**
- are a man with a sexual partner who is pregnant.
- take certain medicines. **INCIVEK may cause serious side effects when taken with certain medicines. Read the section "What should I tell my healthcare provider before taking INCIVEK?"**

Talk to your healthcare provider before taking INCIVEK if any of the above applies to you.

What should I tell my healthcare provider before taking INCIVEK?

Before you take INCIVEK, tell your healthcare provider if you:

- have certain blood problems, such as low red blood cell count (anemia)
- have liver problems other than hepatitis C infection

- have hepatitis B infection
- have Human Immunodeficiency Virus (HIV) infection or any other problems with your immune system
- history of gout or high uric acid levels in your blood
- have had an organ transplant
- plan to have surgery
- have any other medical condition
- are breastfeeding. It is not known if INCIVEK passes into your breast milk. You and your healthcare provider should decide if you will take INCIVEK or breastfeed. You should not do both.

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

INCIVEK and other medicines can affect each other. This can cause you to have too much or not enough INCIVEK or your other medicines in your body, and cause side effects that can be serious or life-threatening. Your healthcare provider may need to change the amount of medicine you take.

Do not take INCIVEK if you take a medicine that contains:

- alfuzosin hydrochloride (Uroxatral[®])
- carbamazepine (Carbatrol[®], Equetro[®], Tegretol[®])
- cisapride (Propulsid[®])
- ergot, including:
 - dihydroergotamine mesylate (D.H.E. 45[®], Migranal[®])
 - ergotamine tartrate (Cafergot[®], Migergot[®], Ergomar[®], Ergostat[®], Medihaler Ergotamine, Wigraine[®], Wigrettes)
 - methylergonovine maleate (Ergotrate[®], Methergine[®])
- lovastatin (Advicor[®], Altoprev[®], Mevacor[®])
- midazolam, when taken by mouth
- phenobarbital
- phenytoin (Dilantin[®], Phenytek[®])
- pimozide (Orap[®])
- rifampin (Rifadin[®], Rifamate[®], Rifater[®])
- sildenafil citrate (Revatio[®]) or tadalafil (Adcirca[®]) for the lung problem, pulmonary artery hypertension (PAH)
- simvastatin (Zocor[®], Vytorin[®], Simcor[®])
- St. John's wort (*Hypericum perforatum*) or products containing St. John's wort
- triazolam (Halcion[®])

Tell your healthcare provider if you are taking or starting to take medicines that contain:

- atorvastatin (Lipitor[®], Caduet[®])
- budesonide (Pulmicort[®], Rhinocort[®], Symbicort[®])
- colchicine (Colcrys[®])
- darunavir (Prezista[®]) and ritonavir (Norvir[®])
- fluticasone (Advair[®], Flonase[®], Flovent[®], Veramyst[®])
- fosamprenavir (Lexiva[®]) and ritonavir (Norvir[®])
- lopinavir and ritonavir (Kaletra[®])
- methylprednisolone (Medrol[®])
- prednisone
- rifabutin (Mycobutin[®])
- salmeterol (Advair[®], Serevent[®])

Your healthcare provider may need to monitor your therapy more closely if you take INCIVEK with the following medicines. Talk to your healthcare provider if you are taking or starting to take medicines that contain:

- alfentanil (Alfenta[®])
- alprazolam (Xanax[®])
- amiodarone (Cordarone[®], Pacerone[®])
- amlodipine (Norvasc[®])
- atazanavir and ritonavir (Reyataz[®], Norvir[®])
- bepridil hydrochloride (Vascor[®], Bepadin)
- bosentan (Tracleer[®])
- clarithromycin (Biaxin[®], Prevpac[®])
- colchicine (Colcrys[®])
- cyclosporine (Gengraf[®], Neoral[®], Sandimmune[®])
- dexamethasone
- digoxin (Lanoxin[®])
- diltiazem (Cardizem[®], Dilacor XR[®], Tiazac[®])
- efavirenz (Sustiva[®], Atripla[®])
- erythromycin (E.E.S.[®], Eryc[®], Ery-Tab[®], Erythrocin[®], Erythrocin Stearate[®])
- escitalopram (Lexapro[®])
- ethinyl estradiol containing birth control methods (Lo Loestrin[™] FE, Norinyl[®], Ortho Tri-Cyclen Lo[®])
- felodipine (Plendil[®])
- fentanyl (Duragesic[®], Subsys[®])
- flecainide (Tambocor[™])
- fluvastatin (Lescol[®], Lescol[®] XL)

- itraconazole (Sporanox[®])
- ketoconazole (Nizoral[®])
- methadone (Dolophine[®], Methadose[™])
- nifedipine (Cardene[®])
- nifedipine (Adalat[®], Procardia[®])
- nisoldipine (Sular[®])
- pitavastatin (Livalo[®])
- posaconazole (Noxafil[®])
- pravastatin (Pravachol[®])
- propafenone (Rythmol[®])
- quinidine (Nuedexta[®])
- repaglinide (Prandin[®])
- rosuvastatin (Crestor[®])
- sildenafil for the treatment of erectile dysfunction (Viagra[®])
- sirolimus (Rapamune[®])
- tacrolimus (Prograf[®])
- tadalafil for the treatment of erectile dysfunction (Cialis[®])
- telithromycin (Ketek[®])
- tenofovir disoproxil fumarate (Atripla[®], Complera[®], Truvada[®], Viread[®])
- trazodone (Desyrel[®], Trialodine, Oleptro[™])
- vardenafil for the treatment of erectile dysfunction (Levitra[®], Staxyn[®])
- verapamil (Calan[®], Covera-HS[®], Isoptin[®], Tarka[®])
- voriconazole (Vfend[®])
- warfarin (Coumadin[®])
- zolpidem (Ambien[®], Edluar[®])

Know the medicines you take. Keep a list of them with you and show it to your healthcare provider and pharmacist each time you get a new medicine.

How should I take INCIVEK?

- Take INCIVEK exactly as your healthcare provider tells you. Your healthcare provider will tell you how much INCIVEK to take and when to take it.
- Take INCIVEK 2 times a day. Each dose should be taken 10 to 14 hours apart. Eat a meal or snack that contains about 20 grams of fat, within 30 minutes before you take each dose of INCIVEK. Talk to your healthcare provider about examples of foods that you can eat that contain about 20 grams of fat. **Always take INCIVEK with food.**
- Swallow INCIVEK tablets whole. Do not chew, crush, break, cut, or dissolve the tablets before you swallow them. Tell your healthcare provider if you have problems swallowing whole tablets.

- If you miss a dose **within 6 hours** of when you usually take it, take your dose with food as soon as possible.
- If you miss a dose and it is **more than 6 hours** after the time you usually take it, **skip that dose only** and take the next dose at your normal dosing schedule.
- Do not stop taking INCIVEK unless your healthcare provider tells you to. If you think there is a reason to stop taking INCIVEK, talk to your healthcare provider before doing so.
- If your healthcare provider tells you to stop taking INCIVEK, you should not start taking it again even if the reason for stopping goes away.
- If you take too much INCIVEK or overdose, call your healthcare provider or local Poison Control Center, or go to the nearest hospital emergency room right away.

What are the possible side effects of INCIVEK?

INCIVEK may cause serious side effects including:

See **“What is the most important information I should know about INCIVEK?”**

Common side effects of INCIVEK in combination with peginterferon alfa and ribavirin include:

- itching
- nausea
- diarrhea
- vomiting
- anal or rectal problems, including:
 - hemorrhoids
 - discomfort or burning around or near the anus
 - itching around or near the anus
- taste changes
- tiredness

It is important to stay hydrated with fluids during INCIVEK combination treatment. Signs and symptoms of dehydration include increased thirst, dry mouth, decreased urine frequency or volume, and dark colored urine. Tell your healthcare provider if you cannot drink fluids, eat, or have severe vomiting or diarrhea.

Tell your healthcare provider about any side effect that bothers you or does not go away.

These are not all the possible side effects of INCIVEK. For more information, ask your healthcare provider or pharmacist.

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 Vertex Pharmaceuticals Incorporated at 1-877-824-4281.

How should I store INCIVEK?

- Store INCIVEK tablets at room temperature between 68°F to 77°F (20°C to 25°C).

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

General information about INCIVEK

It is not known if treatment with INCIVEK will prevent you from infecting another person with the hepatitis C virus during treatment or if you do not respond to treatment.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use INCIVEK for a condition for which it was not prescribed. Do not give INCIVEK to other people, even if they have the same symptoms or condition you have. It may harm them.

This Medication Guide summarizes the most important information about INCIVEK. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about INCIVEK that is written for healthcare professionals.

For more information, go to www.incivek.com or call 1-877-824-4281.

What are the ingredients in INCIVEK?

Active ingredient: telaprevir

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, D&C Red No. 40, dibasic calcium phosphate (anhydrous), FD&C Blue No. 2, hypromellose acetate succinate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium lauryl sulfate, sodium stearyl fumarate, talc, and titanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for

Vertex Pharmaceuticals Incorporated

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