Dispense with Patient Information Sheet available at:
www.drreddys.com/pi/nintedanibcaps.pdf

Patient Information
Nintedanib (nin-**ted**-a-nib**) Capsules**

What is the most important information I should know about nintedanib capsules?

- Nintedanib capsules can cause birth defects or death to an unborn baby. Women should not become pregnant while taking nintedanib capsules. Women who are able to become pregnant should have a pregnancy test before starting treatment with nintedanib capsules.
- Women who are able to become pregnant should use highly effective birth control at the start of treatment, during treatment, and for at least 3 months after treatment. Talk with your doctor about what birth control method is right for you during this time.
- Birth control pills may not work as well in women having vomiting, diarrhea, or other problems reducing the drug absorption. If you have any of these problems, talk with your doctor about which highly effective birth control method is right for you.
- If you become pregnant or think you are pregnant while taking nintedanib capsules, tell your doctor right away.

What is nintedanib?

- Nintedanib is a prescription medicine used:
  - to treat adults with a lung disease called idiopathic pulmonary fibrosis (IPF).
  - to treat adults with a long-lasting (chronic) interstitial lung disease in which lung fibrosis continues to worsen (progress).
- It is not known if nintedanib capsules are safe and effective in children.

What should I tell my doctor before taking nintedanib capsules?
Before you take nintedanib capsules, tell your doctor about all of your medical conditions, including if you:

- have liver problems.
- have heart problems.
- have a history of blood clots.
- have a bleeding problem or a family history of a bleeding problem.
- have had recent surgery in your stomach (abdominal) area.
- are a smoker.
- are pregnant or plan to become pregnant. Nintedanib capsules can harm your unborn baby. Nintedanib capsules can cause birth defects or death to an unborn baby. See **"What is the most important information I should know about nintedanib capsules?"**
- are breastfeeding or plan to breastfeed. It is not known if nintedanib passes into your breast milk. You **should not** breastfeed while taking nintedanib capsules.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements such as St. John's wort. Keep a list of the medicines you take and show it to your doctor and pharmacist when you get a new medicine.

How should I take nintedanib capsules?

- Take nintedanib capsules exactly as your doctor tells you to take it.
- Your doctor will tell you how much nintedanib capsules to take and when to take them.
- Take nintedanib capsules with food. Swallow the nintedanib capsules whole with a liquid.
- **Do not** chew, crush, or open nintedanib capsules. If you or your caregiver accidently comes in contact with the content of the capsule, wash hands well right away.
- If you miss a dose of nintedanib capsules, take your next dose at your regular time. **Do not** take the missed dose.
- **Do not** take more than 300 mg of nintedanib capsules in 1 day.
- If you take too much nintedanib capsules, call your doctor or go to the nearest hospital emergency room right away.
- Your doctor should do certain blood tests before you start taking nintedanib capsules.

What are the possible side effects of nintedanib capsules?
Nintedanib capsules may cause serious side effects, including:

- **See "What is the most important information I should know about nintedanib capsules?"**
- **liver problems.** Call your doctor right away if you have unexplained symptoms such as yellowing of your skin or the white part of your eyes (jaundice), dark or brown (tea colored) urine, pain on the upper right side of your stomach area (abdomen), bleeding or bruising more easily than normal, feeling tired, or loss of appetite. Your doctor will do blood tests to check how well your liver is working before starting and during your treatment with nintedanib capsules.
- **diarrhea, nausea, and vomiting.** While you are taking nintedanib capsules, your doctor may recommend that you drink fluids or take medicine to treat these side effects. Tell your doctor if you have diarrhea, nausea, or vomiting or if these symptoms do not go away or become worse. Tell your doctor if you are taking over-the-counter laxatives, stool softeners, and other medicines or dietary supplements that can cause diarrhea.
- **heart attack.** Tell your doctor right away if you have symptoms of a heart problem. These symptoms may include chest pain or pressure, pain in your arms, back, neck or jaw, or shortness of breath.
- **stroke.** Tell your doctor right away if you have symptoms of a stroke. These symptoms may include numbness or weakness on

Continued on other side

1 side of your body, trouble talking, headache, or dizziness.

- **bleeding problems.** Nintedanib capsules may increase your chances of having bleeding problems. Tell your doctor if you have unusual bleeding, bruising, or wounds that do not heal. Tell your doctor if you are taking a blood thinner, including prescription blood thinners and over-the-counter aspirin.
- **tear in your stomach or intestinal wall (perforation).** Nintedanib capsules may increase your chances of having a tear in your stomach or intestinal wall. Tell your doctor if you have pain or swelling in your stomach area.
- **increased protein in your urine (proteinuria).** Nintedanib capsules may increase your chances of having protein in your urine. Tell your doctor if you have any signs and symptoms of protein in the urine such as foamy urine, swelling, including in your hands, arms, legs, or feet, or sudden weight gain.

The most common side effects of nintedanib capsules are diarrhea, nausea, stomach pain, vomiting, liver problems, decreased appetite, headache, weight loss, and high blood pressure.

These are not all the possible side effects of nintedanib capsules. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store nintedanib capsules?

- Store nintedanib capsules at room temperature between 20°C to 25°C (68°F to 77°F).
- Keep nintedanib capsules dry and protect from high heat.

Keep nintedanib capsules and all medicines out of the reach of children.

General information about the safe and effective use of nintedanib capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use nintedanib capsules for a condition for which it was not prescribed. Do not give nintedanib capsules to other people, even if they have the same symptoms you have. It may harm them. This Patient Information leaflet summarizes the most important information about nintedanib capsules. If you would like more information, talk to your doctor. You can ask your pharmacist or doctor for information about nintedanib capsules that is written for health professionals.

For more information about nintedanib capsules call Dr. Reddy's Laboratories Inc. at 1-888-375-3784.

What are the ingredients in nintedanib capsules?

Active ingredient: nintedanib

Inactive ingredients: Fill Material: hard fat, medium chain triglycerides, polysorbate, sorbitan monooleate. Capsule Shell: gelatin, glycerin, titanium dioxide, iron oxide red and iron oxide yellow. The imprinting ink contains black iron oxide, propylene glycol and shellac.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Rx only

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Dr.Reddy's