

Facts About Crohn's Disease

What is Crohn's Disease?

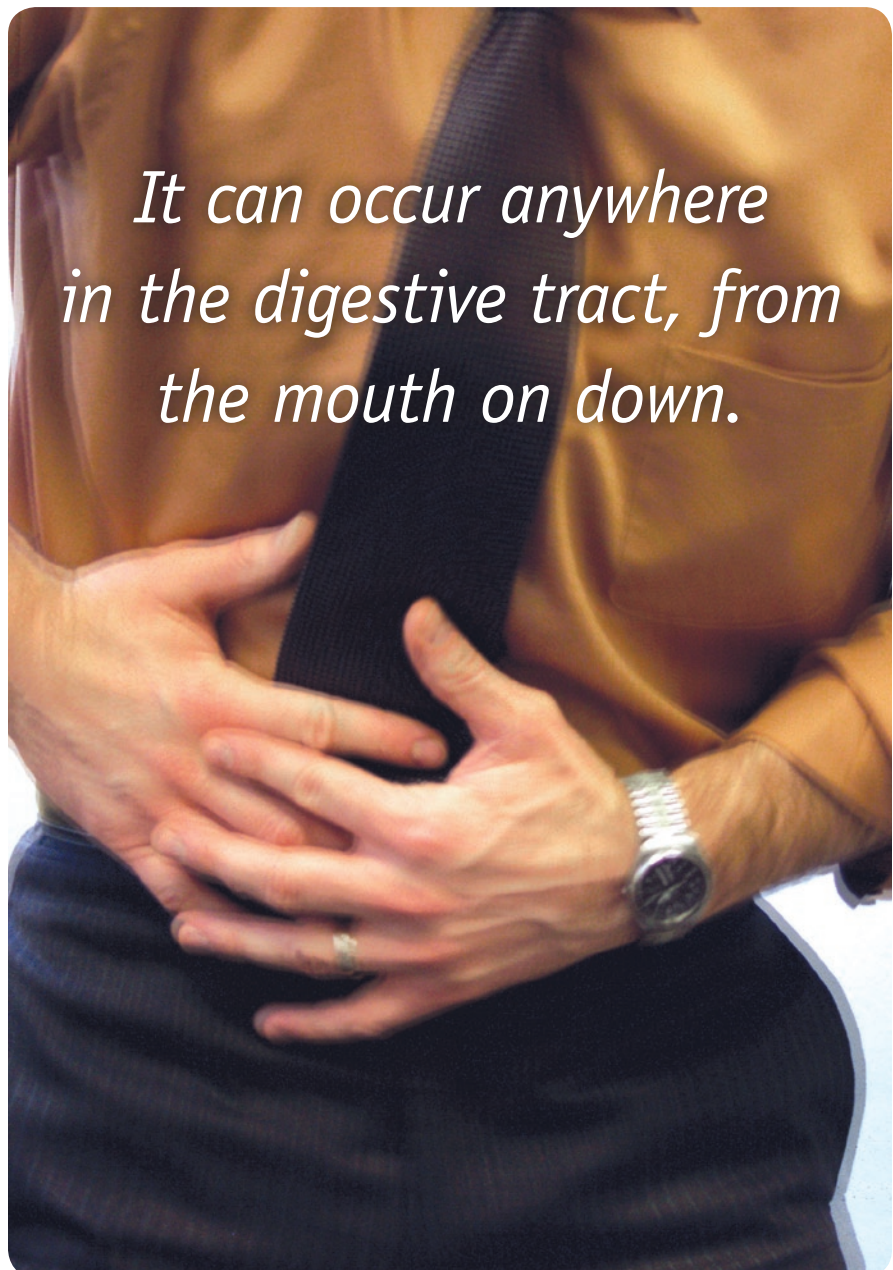
- It is a chronic inflammatory condition of the digestive tract.
- It has been diagnosed in adults and children, and affects about a half million Americans.
- It can occur anywhere in the digestive tract, from the mouth on down. It most commonly affects the lower part of the small intestine.
- It is incurable, but there are treatments available to relieve symptoms.

Recent Approvals

Cimzia (certolizumab pegol):

On April 28, 2008, FDA approved Cimzia to treat adults with moderate to severe Crohn's Disease who have not responded to conventional therapies. The new drug was approved with a Medication Guide. Patients treated with Cimzia will receive an injection every two weeks for the first three injections. Once benefit has been established, the drug should be given once every four weeks.

The most common side effects of Cimzia are headache, upper respiratory infections, abdominal pain, injection site reactions, and nausea. Patients taking Cimzia are at increased risk for serious adverse effects, including serious infections that can lead to hospitalization or death. Because Cimzia affects the immune system, Cimzia can lower the body's ability to fight opportunistic infections such as tuberculo-



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Photo Illustration: FDA/Michael Ermarth

sis. People who take Cimzia should be educated about how to identify an infection and be instructed to contact their health care professional at the first sign of infection. In cases of serious infection, the drug should be stopped immediately.

Cimzia also may cause lymphomas (a form of cancer). Although an increased risk of tumors was not seen in studies of Cimzia, the modest size and relatively short duration of the controlled studies prevents any firm conclusion. Post-marketing studies will be required to obtain long-term safety data.

For more information on the approval of Cimzia for Crohn's Disease, see FDA's Press Release: www.fda.gov/bbs/topics/NEWS/2008/NEW01821.html

Tysabri (natalizumab):

FDA has announced that it will permit the sale of Tysabri (natalizumab) for use by sufferers of moderate to severe Crohn's disease.

Tysabri had already been approved in the United States and the European Union for use against the most advanced cases of multiple sclerosis.

Clinical trials have indicated that the drug is effective in limiting damage by inflammatory immune cells associated with Crohn's disease by keeping these cells from penetrating the intestine wall.

Tysabri should be administered intravenously by trained professionals. Because of potentially serious adverse events, Tysabri will carry a boxed warning and patients must be enrolled in a risk minimization action plan called the Touch (Tysabri Outreach Unified Commitment to Health) Prescribing Program.

For more information on the approval of Tysabri for Crohn's disease, see FDA's Press Release: www.fda.gov/bbs/topics/NEWS/2008/NEW01775.html

How Do You Get It?

Medical experts aren't sure. According to the National Institutes of Health,

the most popular theory is that the body's immune system reacts abnormally in people with Crohn's disease, mistaking bacteria, foods, and other substances as things that don't belong in the body. The immune system attacks these "invaders," often causing white blood cells to accumulate in the intestinal lining. This causes chronic inflammation that can lead to ulcerations and bowel injury.

What are the Symptoms?

The most common symptoms are abdominal pain—often in the lower right area—and diarrhea. Rectal bleeding, weight loss, arthritis, skin problems, and fever may occur. Bleeding may be serious and persistent, leading to anemia.

How is It Diagnosed?

A thorough physical exam and a series of tests may be required to diagnose Crohn's disease.

What are the Possible Complications?

- A blockage caused by thickening of the intestine is the most common complication of Crohn's disease.
- Sores or ulcers, called "fistulas," that tunnel through the affected area into surrounding tissues. Fistulas often become infected.
- Small tears called fissures may develop in the lining of the mucus membrane of the anus.
- Nutritional effects such as deficiencies of proteins, calories, and vitamins.
- Arthritis, skin problems, inflammation in the eyes or mouth, kidney stones, gallstones, and other diseases of the liver and biliary system.

Research has shown that pregnancy and delivery are usually not impaired in women with Crohn's disease. Still, women with the disease should consult with their doctors before pregnancy.

What are the Treatments?

Available treatments include drugs, nutritional supplements and surgical removal of affected parts of the intestine. Actual treatment depends on the location and severity of disease, complications, and the person's response to previous medical treatments.

Medical therapies include

- anti-inflammation drugs
- cortisone or steroids
- immune system suppressors
- antibiotics
- anti-diarrheal drugs and fluid replacements.

In addition to Tysabri and Cimzia, FDA has approved Remicade (infliximab) and Humira (adalimumab). Both products are approved for the treatment of adults with moderate to severe Crohn's disease that doesn't respond to standard therapies.

In addition, Remicade is approved for the treatment of children 6 years and older, and for the treatment of adult patients with open, draining fistulas. Humira is also approved for the treatment of patients with moderate to severe Crohn's disease who have lost response or are intolerant to Remicade. [FDA](http://www.fda.gov)

For More Information

FDA Press Release: FDA Approves Tysabri to Treat Moderate-to-Severe Crohn's Disease
www.fda.gov/bbs/topics/NEWS/2008/NEW01775.html

National Institutes of Health
<http://digestive.niddk.nih.gov/ddiseases/pubs/crohns/index.htm>

Crohn's & Colitis Foundation of America
www.ccfa.org/info/about/crohns