

From the CCHR data bank.

**International warnings, methylphenidate, Ritalin, etc.**

Brand Names:

Ritalin, Concerta, Daytrana, Metadate

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18)

Date:

April 1, 2016 Country: Denmark

Side Effects:

Heart Problems, Cardiovascular Problems

Summary:

**The Danish Pharmacovigilance Update, published by the Danish Medicines Agency, included a section about an Adverse Drug Reaction report of a child who went in to cardiac arrest (when the heart stops beating) after treatment with methylphenidate (also known as Ritalin). The report explained the need for doctors to be aware of and pre-screen for preexisting heart conditions before prescribing this drug, and that there should be ongoing monitoring of a patient's cardiovascular health while on it.**

Source:

"Reports of cardiac arrest after treatment with methylphenidate," Danish Medicines Agency, Danish Pharmacovigilance Update, No. 4, Vol. 7, April 2016. [link]

<< Close

Warning ID: 665

Brand Names:

Ritalin, Concerta, Daytrana, Metadate, Strattera, Vyvanse

Generic Names:

Methylphenidate, Atomoxetine, Lisdexamfetamine, Dexamfetamine

Drug Classes:

Stimulant, Antidepressant

Ages:

Children (under 18), Adults (18 and older)

Date:

January 1, 2016 Country: Denmark

Side Effects:

Heart Problems, Cardiovascular Disorders, High Blood Pressure, Heart Attack, Irregular Heartbeat, Chest Pain, Death

Summary:

**The Danish Pharmacovigilance Update, from the Danish Medicines Agency, reported that they had received 103 reports of suspected cardiovascular adverse reactions associated with ADHD drugs (69 reports on methylphenidate, 24 reports on atomoxetine, 9 reports on lisdexamfetamine and 1 report on dexamfetamine). Of the 103 reports, 66 of them were submitted within the last 5 years. Three of these reports were regarding deaths in connection to methylphenidate due to**

cardiovascular problems. One report described a child who suffered cardiac arrest (when the heart stops beating) leading to permanent injuries while taking Concerta (methylphenidate). Cardiovascular reactions reported included tachycardia (abnormally fast heart rate), hypertension (high blood pressure), myocardial infarction (heart attack), atrial fibrillation (irregular heartbeat), angina pectoris (chest pain due to lack of blood to the heart), and more. In addition, it was mentioned that "The patients who were treated for extended periods had more severe cardiovascular adverse reactions than those who received treatment for less than a year."

Source:

Danish Medicines Agency, "ADHD medicines and cardiovascular adverse reactions," Danish Medicines Agency, Danish Pharmacovigilance Update, No. 1, Vol 7, pp. 4-11, Jan 2016. [link]

<< Close

Warning ID: 655

Brand Name:

Daytrana

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Adults (18 and over)

Date:

June 24, 2015 Country: United States

Side Effect:

Skin Problems

Summary:

**The FDA warned users that the Daytrana patch, used in ADHD treatments, was causing permanent skin color changes. While not harmful, these effects are disfiguring, and they are thought to be irreversible.**

Source:

"Daytrana Patch (methylphenidate transdermal system): Drug Safety Communication - Permanent Skin Color Changes" FDA MedWatch, June 24 2015. [link]

<< Close

Warning ID: 656

Brand Names:

Biphentin, Concerta, Ritalin, Ritalin SR, Concerta, Daytrana, Metadate

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

April 21, 2015 Country: Canada

Side Effect:

Priapism

Summary:

**Health Canada issued a letter to healthcare professionals about the risk of children and adults developing priapism (a prolonged and often painful erection) while taking methylphenidate (Biphentin, Concerta, Ritalin, Ritalin SR and all other generic versions). The warning says that priapism has been very rarely reported in patients, including children, taking methylphenidate products, specifically after increasing the dose or stopping the product even for a short period of time. The prescribing information for methylphenidate products was updated to include this information.**

Source:

"Methylphenidate Products Risk of Priapism," Health Canada, 21 Apr 2015. [link]

<< Close

Warning ID: 609

Brand Names:

Adderall, Adderall XR, Concerta, Daytrana, Desoxyn, Dexedrin, Focalin, Focalin XR, Metadate CD, Methylin, Quillivant XR, Ritalin, Ritalin LA, Ritalin SR, Strattera and Vyvanse.

Generic Names:

Dextroamphetamine & Amphetamine, Methylphenidate, Methamphetamine, Dextroamphetamine, Dexmethylphenidate, Atomoxetine, Lisdexamfetamine

Drug Classes:

Stimulant, Antidepressant

Ages:

Adults (18 and over)

Date:

April 1, 2015 Country: United States

Side Effect:

Muscle Problems

Summary:

**The FDA updated the Adverse Reactions on drug labels of specific stimulant drugs to include the side effect rhabdomyolysis, a breakdown of muscle tissue that releases muscle fiber contents into the blood. This condition can be harmful to the kidney and cause kidney damage. The drugs included on this warning were Adderall, Adderall XR, Concerta, Daytrana, Desoxyn, Dexedrin, Focalin, Focalin XR, Metadate CD, Methylin (Chewables and Oral Solution), Quillivant XR, Ritalin, Ritalin LA, Ritalin SR, Strattera and Vyvanse.**

Source:

"Stimulants used to treat Attention Deficit Hyperactivity Disorder" FDA MedWatch, April 2015. [link]

<< Close

Warning ID: 608

Brand Names:

Adderall XR, Biphentin, Concerta, Dexedrine, Intuniv XR, Ritalin, Ritalin SR, Strattera, Vyvanse

Generic Names:

Dextroamphetamine & Amphetamine, Methylphenidate, Dextroamphetamine, Guanfacine, Atomoxetine, Lisdexamfetamine

Drug Classes:

Stimulant, Antihypertensive, Antidepressant

Ages:

Adults (18 and over)

Date:

March 30, 2015 Country: Canada

Side Effects:

Suicidal Ideation, Suicidal Behavior, Suicide Attempts, Completed Suicide

Summary:

**Health Canada issued an alert warning that ADHD Drugs may increase the risk of suicidal thoughts and behaviors in some people. The alert said, "Stronger, clearer warnings on the risk of suicidal thoughts and behaviors are being incorporated into the prescribing information for drugs used in the management of Attention Deficit Hyperactivity Disorder (ADHD). The new warnings advise that there have been reports of suicide-related events in patients treated with ADHD drugs. The reports involved thoughts of suicide, suicide attempts, and in a very small number of cases, completed suicide. These events have been reported at various times during treatment, particularly at the start or during dose changes, and also after stopping the drug treatment." The drugs named in this warning are Adderall XR (mixed salts amphetamine extended release), Biphentin (methylphenidate controlled release), Concerta (methylphenidate extended release), Dexedrine (dextroamphetamine sulfate), Intuniv XR (guanfacine extended release), Ritalin (methylphenidate), Ritalin SR (methylphenidate extended release), Strattera (atomoxetine) and Vyvanse (lisdexamfetamine dimesylate).**

Source:

"ADHD drugs may increase risk of suicidal thoughts and behaviours in some people? benefits still outweigh risks," Health Canada, Government of Canada, 30 Mar 2015. [link]

<< Close

Warning ID: 657

Brand Names:

Ritalin, Concerta, Daytrana, Metadate

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Adults (18 and over)

Date:

February 1, 2015 Country: Denmark

Side Effects:

Heart Problems, Cardiovascular Problems, Death

Summary:

**The Danish Health and Medicines Authority (DHMA), reported that they are keeping a watch on ADHD drugs, including methylphenidate. Over the past four years, they have received three Adverse Drug Reaction reports of fatal outcomes in connection with methylphenidate treatment. All three reports describe cardiovascular disturbances prior to death. In addition, one report was received of a boy who went in to cardiac arrest while taking Concerta and suffered permanent injuries. Because of this the DHMA is telling the public that they are focused on ADHD drugs and their possible adverse reactions, especially regarding cardiovascular effects.**

Source:

Sundhedsstyrelsen, "DHMA has focus on ADHD medicines and cardiovascular disturbances," Danish Pharmacovigilance Update #2, February 2015, Vol 6. [link]

<< Close

Warning ID: 658

Brand Names:

Ritalin, Concerta, Daytrana, Metadate

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

October 1, 2014 Country: Australia

Side Effect:

Priapism

Summary:

**Australia's Therapeutic Goods Administration (TGA) published in their Medicines Safety Update an advisory to health care professionals that in very rare cases treatment with methylphenidate (Ritalin and Concerta) may potentially lead to prolonged and sometimes painful erections (called priapism). Priapism can develop after some time after drug initiation, often subsequent to an increase in dose, and has also been observed during a period of methylphenidate withdrawal. While this risk applies to all use in males, the greatest concern is regarding pre-pubertal boys, who might not recognise the problem or may be too embarrassed to seek help if it occurs.**

Source:

TGA, "Methylphenidate and priapism" Medicines Safety Update, Volume 5, Number 5, October 2014. [link]

<< Close

Warning ID: 659

Brand Names:

Concerta, Daytrana, Focalin, Focalin XR, Metadate CD, Metadate ER, Methylin, Methylin ER, Quillivant XR, Ritalin, Ritalin LA, Ritalin SR

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

December 17, 2013 Country: United States

Side Effects:

Reproductive System Disorders, Priapism

Summary:

**The FDA warned that methylphenidate products may in rare instances cause prolonged and sometimes painful erections known as priapism. Based on a recent review of methylphenidate products, FDA updated drug labels and patient Medication Guides to include information about**

**the rare but serious risk of priapism. If not treated right away, priapism can lead to permanent damage to the penis.**

Source:

"Methylphenidate ADHD Medications: Drug Safety Communication - Risk of Long-lasting Erections," FDA, December 17, 2013. [link]

<< Close

Warning ID: 660

Brand Name:

Quillivant XR

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Adults (18 and over)

Date:

August 1, 2013 Country: United States

Side Effects:

Cardiovascular Problems, Raynaud's Phenomenon, Restricted Blood Flow

Summary:

**The FDA warned Quillivant XR is associated with peripheral vasculopathy [narrowing of blood vessels that restricts blood flow to the extremities], including Raynaud's phenomenon [a disease characterized by spasm of the arteries in the extremities].**

Source:

"Quillivant XR (Methylphenidate) Extended-release Oral Suspension," FDA Medwatch, August 2013. [link]

<< Close

Warning ID: 548

Brand Name:

Concerta

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

June 1, 2013 Country: United States

Side Effects:

Restricted Blood Flow, Peripheral Vasculopathy, Raynaud's Phenomenon, Cardiovascular Problems

Summary:

**The FDA updated Concerta's safety label to include warnings about peripheral vasculopathy (restricted blood flow, caused by narrowing of the blood vessels in the legs and sometimes arms), including Raynaud's phenomenon. Raynaud's phenomenon is a condition in which blood vessels**

**spasm and block blood flow to the fingers, toes, ears and nose in reaction to cold or emotional stress. These rare symptoms can include ulcers and/or soft tissue breakdown in the fingers.**

Source:

"Concerta (methylphenidate HCl) Extended-Release tablets," FDA Medwatch, June 2013. [link]

<< Close

Warning ID: 549

Brand Name:

Daytrana

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

June 1, 2013 Country: United States

Side Effects:

Restricted Blood Flow, Peripheral Vasculopathy, Raynaud's Phenomenon, Cardiovascular Problems

Summary:

**The FDA updated Daytrana's safety label to include warnings about peripheral vasculopathy (restricted blood flow, caused by narrowing of the blood vessels in the legs and sometimes arms), including Raynaud's phenomenon. These effects were observed at therapeutic doses in all age groups throughout the course of treatment. [Raynaud's phenomenon is a condition in which blood vessels spasm and block blood flow to the fingers, toes, ears and nose in reaction to cold or emotional stress. These rare symptoms can include ulcers and/or soft tissue breakdown in the fingers.]**

Source:

"Daytrana (methylphenidate) transdermal system," FDA Medwatch, June 2013. [link]

<< Close

Warning ID: 551

Brand Names:

Focalin, Focalin XR

Generic Name:

Dexmethylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

June 1, 2013 Country: United States

Side Effects:

Restricted Blood Flow, Peripheral Vasculopathy, Raynaud's Phenomenon, Cardiovascular Problems

Summary:

**The FDA updated Focalin's safety label to include warnings about peripheral vasculopathy (restricted blood flow, caused by narrowing of the blood vessels in the legs and sometimes arms), including Raynaud's phenomenon. Raynaud's phenomenon is a condition in which blood vessels spasm and block blood flow to the fingers, toes, ears and nose in reaction to cold or emotional stress. These rare symptoms can include ulcers and/or soft tissue breakdown in the fingers.**

Source:

"Focalin (dexamethylphenidate hydrochloride) Tablets and Focalin XR (Extended-Release) Capsules," FDA Medwatch, June 2013. [link]

<< Close

Warning ID: 552

Brand Name:

Metadate CD

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

June 1, 2013 Country: United States

Side Effects:

Restricted Blood Flow, Peripheral Vasculopathy, Raynaud's Phenomenon, Cardiovascular Problems

Summary:

**The FDA updated Metadate CD's safety label to include warnings about peripheral vasculopathy (restricted blood flow, caused by narrowing of the blood vessels in the legs and sometimes arms), including Raynaud's phenomenon. Raynaud's phenomenon is F65**

Source:

"Metadate CD (methylphenidate HCl) Extended-Release Capsules," FDA Medwatch, June 2013. [link]

<< Close

Warning ID: 553

Brand Name:

Methylin

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

June 1, 2013 Country: United States

Side Effects:

Restricted Blood Flow, Peripheral Vasculopathy, Raynaud's Phenomenon, Cardiovascular Problems

Summary:



**The FDA updated Methylin's safety label to include warnings about peripheral vasculopathy (restricted blood flow, caused by narrowing of the blood vessels in the legs and sometimes arms), including Raynaud's phenomenon. Raynaud's phenomenon is a condition in which blood vessels spasm and block blood flow to the fingers, toes, ears and nose in reaction to cold or emotional stress. These rare symptoms can include ulcers and/or soft tissue breakdown in the fingers.**

Source:

"Methylin (methylphenidate HCl) Oral Solution and Chewable tablets," FDA Medwatch, June 2013. [link]

<< Close

Warning ID: 554

Brand Names:

Ritalin, Ritalin SR, Ritalin LA

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

June 1, 2013 Country: United States

Side Effects:

Restricted Blood Flow, Peripheral Vasculopathy, Raynaud's Phenomenon, Cardiovascular Problems

Summary:

**The FDA updated Ritalin's safety label to include warnings about peripheral vasculopathy (restricted blood flow, caused by narrowing of the blood vessels in the legs and sometimes arms), including Raynaud's phenomenon. Raynaud's phenomenon is a condition in which blood vessels spasm and block blood flow to the fingers, toes, ears and nose in reaction to cold or emotional stress. These rare symptoms can include ulcers and/or soft tissue breakdown in the fingers.**

Source:

"Ritalin (methylphenidate hydrochloride) Tablets, Ritalin SR (Extended-Release Tablets), and Ritalin LA (Extended-Release Capsules)," FDA Medwatch, June 2013. [link]

<< Close

Warning ID: 543

Brand Names:

Focalin, Focalin XR

Generic Name:

Dexmethylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

May 1, 2012 Country: United States

Side Effects:

Skin Reactions, Serious Allergic Reactions, Swelling, Fever, Breathing Problems, Seizures, Slowed Growth, Blurred Vision, Eye Problems

Summary:

**The FDA updated Focalin's and Focalin XR's drug labels to include that Focalin is contraindicated in patients known to be hypersensitive to methylphenidate or other components of the product. Hypersensitivity reactions, including angioedema [swelling beneath the skin] and anaphylaxis [a life-threatening allergic reaction to a toxin or substance foreign to the body], have been observed in patients treated with methylphenidate. Additional serious side effects were added to the label.**

Source:

"Focalin (dexmethylphenidate hydrochloride) and Focalin XR (dexmethylphenidate hydrochloride) Extended-Release Capsules," FDA Medwatch, May 2012. [link]

<< Close

Warning ID: 534

Brand Names:

Ritalin, Concerta, Metadate, Daytrana

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18)

Date:

June 1, 2010 Country: New Zealand

Side Effects:

Depression, Suicidal Ideation, Hostility, Anxiety, Agitation, Psychosis, Mania

Summary:

**New Zealand's drug regulatory agency MedSafe has reviewed recent changes to the European product information for methylphenidate (Ritalin, Concerta, Metadate, Daytrana) and recommended that the New Zealand data sheets be updated to include these changes. The changes outline that patients being considered for methylphenidate treatment should be carefully screened for cardiovascular risk, heart disease and psychiatric disorders, including any family risk factors. Also, because methylphenidate can cause or worsen some psychiatric disorders (such as depression, suicidal thoughts, hostility, anxiety, agitation, psychosis and mania) patient's "psychiatric well being" should be monitored.**

Source:

"Methylphenidate - updated guidance when treating children," New Zealand Medicines and Medical Devices Safety Authority, June 2010. [link]

<< Close

Warning ID: 533

Brand Name:

Ritalin

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18)

Date:

April 1, 2010 Country: United States

Side Effects:

Cerebrovascular Problems, Stroke, Brain Bleeding, Structural Brain Changes

Summary:

**The FDA added warnings to Ritalin's drug package insert that stated there are additional cerebrovascular (relating to the brain and its blood vessels) side effects associated with Ritalin use. It also warned of additional drug interaction side effects.**

Source:

Ritalin LA (methylphenidate hydrochloride) extended-release capsules, FDA Medwatch, April 2010. [link]

<< Close

Warning ID: 529

Brand Names:

Focalin, Focalin XR, Dexedrine, Dexedrine Spansules, Dextrostat, Vyvanse, Desoxyn, Concerta, Daytrana, Metadate CD, Metadate ER, Methylin, Methylin ER, Ritalin, Ritalin LA, Ritalin SR, Adderall, Adderall XR, Cylert

Generic Names:

Dexmethylphenidate, Dextroamphetamine, Lisdexamfetamine, Methamphetamine, Methylphenidate, Amphetamine and Dextroamphetamine, Pemoline

Drug Class:

Stimulant

Ages:

Children (under 18)

Date:

June 15, 2009 Country: United States

Side Effects:

Death, Sudden Death

Summary:

**The FDA reported on a study reviewing 564 healthy Children taking stimulants who died suddenly. The study authors concluded that there may be an association between the use of stimulant medications and sudden death in healthy Children.**

Source:

"Stimulant Medications used in Children with Attention-Deficit/Hyperactivity Disorder - Communication about an Ongoing Safety Review," FDA MedWatch, June 15, 2009. [link]

<< Close

Warning ID: 528

Brand Names:

Concerta, Ritalin, Ritalin LA

Generic Name:

Methylphenidate

Drug Class:  
Stimulant  
Ages:  
Children (under 18)  
Date:  
February 1, 2009 Country: Australia  
Side Effects:  
Abnormal Behavior, Emotional Changes, Mania, Psychosis

Summary:  
**The Australian Therapeutic Goods Administration reported that a boxed warning (the strongest warning) was placed onto the ADHD psychostimulant drug methylphenidate (Concerta and Ritalin) for drug dependence. It warns that chronic abuse of methylphenidate can lead to a marked tolerance and psychological dependence with varying degrees of abnormal behavior and frank psychotic episodes can also occur.**

Source:  
"Boxed Warning, Contraindications and strengthened Precautions for Methylphenidate," Janssen-Cilag, February 2009.

<< Close  
Warning ID: 526

Brand Names:  
Ritalin, Concerta, Metadate  
Generic Name:  
Methylphenidate  
Drug Class:  
Stimulant  
Ages:  
Children (under 18)  
Date:  
January 23, 2009 Country: France  
Side Effects:  
Heart Problems, Cardiac Events, Mania, Psychosis, Stunted Growth

Summary:  
**France's equivalent of the FDA issued recommendations for the monitoring of patients prescribed methylphenidate, stating that patients should be monitored for cardiac problems, emerging psychiatric conditions, and the size and weight of the patient, during treatment, due to slower growth observed in children treated during a long period.**

Source:  
L'agence europeenne du mdicament (EMA), "Point d'information" Agence francaise de securite sanitaire des produits de sante (AFSAPPS), January 23, 2009.

<< Close  
Warning ID: 523

Brand Name:  
Daytrana  
Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18)

Date:

February 1, 2008 Country: United States

Side Effects:

Nervous System Disorders, Skin Problems, Skin Reactions, Gastrointestinal Symptoms, Immune System Disorders, Heart Problems, Cardiac Events, Blood Pressure Changes, Hair Loss, Eye Disorders

Summary:

**The FDA's MedWatch added the following information to the Daytrana (methylphenidate) safety label: Skin redness or itching is common with Daytrana, and small bumps on the skin may also occur in some patients. If any swelling or blistering occurs, the patch should not be worn and the patient should be seen by the prescriber. Also added were post-marketing reports of adverse reactions such as palpitations (irregular beats of the heart), eye disorders, abdominal pain, application site reactions, bruising, burning, certain immune system disorders, heart rate increased, blood pressure increased, nervous system disorders, certain psychiatric disorders and loss of hair.**

Source:

"Detailed View: Safety Labeling Changes Approved By FDA Center for Drug Evaluation and Research (CDER) - February 2008" MedWatch, February 2008.

<< Close

Warning ID: 519

Brand Name:

Ritalin

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

October 17, 2007 Country: Japan

Side Effects:

Dependence, Addiction, Medication Abuse

Summary:

**The Health, Labor and Welfare Ministry in Japan decided to remove Ritalin from their list of approved medicines to treat depression because of the large amount of abuse that had been going on with Ritalin and wanted to prevent any further increase of this.**

Source:

"Psychotropic drug Ritalin no longer for depression patients," Breitbart.com, 17 Oct 2007;

"Antidepressant Ritalin to be delisted because of abuse," Daily Yomiuri Online, October 19, 2007.

<< Close

Warning ID: 294

Brand Names:

Adderall, Concerta, Daytrana, Desoxyn, Dexedrine, Focalin, Metadate CD, Methylin, Ritalin, Ritalin SR, Ritalin LA, Strattera

Generic Names:

Amphetamine and Dextroamphetamine, Methylphenidate, Methamphetamine, Dextroamphetamine, Dexmethylphenidate, Atomoxetine

Drug Classes:

Antidepressant, Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

February 21, 2007 Country: United States

Side Effects:

Mania, Psychosis, Stroke, Cerebrovascular Events, Heart Problems, Cardiac Events

Summary:

**The FDA directed ADHD drug manufacturers to distribute "patient friendly" guides to consumers warning about serious psychiatric and cardiovascular problems, including stroke, heart attack, sudden death and psychotic reactions caused by ADHD drugs.**

Source:

"FDA Directs ADHD Drug Manufacturers to Notify Patients about Cardiovascular Adverse Events and Psychiatric Adverse Events," FDA News, February 21, 2007.

<< Close

Warning ID: 514

Brand Name:

Ritalin

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18)

Date:

November 6, 2006 Country: United Kingdom

Side Effects:

Heart Problems, Cardiac Events

Summary:

**The UK Medicines and Healthcare products Regulatory Agency updated the product information for methylphenidate (Ritalin) to advise about serious cardiovascular adverse effects and to recommend that methylphenidate should not be used in Children or adolescents with known serious structural cardiac abnormalities.**

Source:

Press Association "Yesterday in parliament" Special Reports, Guardian Unlimited Politics, November 7, 2006.

<< Close

Warning ID: 293

Brand Names:

Strattera, Ritalin, Dexedrine

Generic Names:

Atomoxetine, Methylphenidate, Dexamphetamine

Drug Classes:

Antidepressant, Stimulant

Ages:

Children (under 18)

Date:

October 18, 2006 Country: Australia

Side Effects:

RITALIN: Headaches, Nausea, Eating Disorders, Depression, Sleepiness, Drowsiness, Fatigue.

STATTERA: Aggression. DEXAMPHETAMINE: Agitation, Insomnia, Heart Problems, Cardiac Events, Abnormally Tight Muscles, Muscle Spasms

Summary:

**The Australian Therapeutic Goods Administration (TGA) ordered manufacturers of Ritalin, Strattera and dexamphetamine to add stronger warnings to their information packaging after receiving 200 complaints about the drugs. The TGA had received 123 reports of adverse reactions involving Ritalin, including complaints that it caused headache, nausea, anorexia, somnolence (sleepiness) and depression; 23 reports about atomoxetine (Strattera), including aggression, and 60 reports about dexamphetamine, including seven of agitation, five of tachycardia (rapid heartbeat) and four reports each of hypertonia (abnormally tight muscles), hyperkinesia (muscle spasm) and insomnia.**

Source:

"ADHD drug risks for kids", The Australian, Matthew Franklin, October 18, 2006.

<< Close

Warning ID: 512

Brand Names:

Adderall XR, Attenade, Biphentin, Concerta, Dexedrine, Ritalin, Ritalin SR, Strattera

Generic Names:

Methylphenidate, Amphetamine and Dextroamphetamine, Atomoxetine, Dexmethylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18)

Date:

September 21, 2006 Country: Canada

Side Effects:

Death, Sudden Death, Agitation, Irritability, Heart Problems, Cardiac Events, Stroke, Cerebrovascular Events, Hallucinations, Delusional Thinking, Sensory Disturbances

Summary:

**Health Canada increased warnings on ADHD drugs due to the "potential for psychiatric adverse events" including agitation and hallucinations. This is in addition to earlier Canadian warnings of cardiovascular risks from ADHD Drugs including cardiac arrest, stroke and sudden death.**

Source:

"New Information Regarding Uncommon Psychiatric Adverse Events For All ADHD Drugs" Information Update, September 21, 2006.

<< Close

Warning ID: 292

Brand Names:

Adderall XR, Attenade, Biphentin, Concerta, Dexedrine, Ritalin, Ritalin SR, Strattera

Generic Names:

Amphetamine and Dextroamphetamine, Dextromethylphenidate, Methylphenidate, Dextroamphetamine, Atomoxetine

Drug Classes:

Antidepressant, Stimulant

Ages:

Children (under 18), Adults (18 and older)

Date:

May 26, 2006 Country: Canada

Side Effects:

Death, Sudden Death, Blood Pressure Changes, Heart Problems, Cardiac Events, Stroke, Cerebrovascular Events

Summary:

**Health Canada issued new warnings of rare heart risks for all drugs prescribed for ADHD, including the risk of sudden death. The public advisory cautioned that the stimulants can increase heart rate and blood pressure and that this can result in "cardiac arrests, strokes or sudden deaths." This warning applies to both Adults and Children.**

Source:

"New cautions regarding rare heart-related risks for all ADHD drugs," Health Canada, 2006-35, May 26, 2006.

<< Close

Warning ID: 510

Brand Name:

Ritalin

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18)

Date:

April 19, 2006 Country: Singapore

Side Effects:

Insomnia, Disturbed Sleep, Gastrointestinal Symptoms, Heart Problems, Cardiac Events, Skin Problems, Skin Reactions

Summary:



**The Singapore Health Sciences Authority said it was reviewing the cardiovascular effects of stimulants. They reported adverse reactions in Children aged between 6 and 12, including disturbed sleep, giddiness, abdominal pain, gastric discomfort, palpitations, rash and itching.**

Source:

"Pay attention to risk of stimulant drugs for kids; Reports of increased health risks have put the spotlight on drugs like Ritalin used to treat attention deficit hyperactivity disorder in Children. Shefali Srinivas reports." Straits Times, April 19, 2006.

<< Close

Warning ID: 509

Brand Names:

Ritalin, Dexedrine

Generic Names:

Methylphenidate, Dexamphetamine

Drug Class:

Stimulant

Ages:

Children (under 18)

Date:

March 28, 2006 Country: Australia

Side Effects:

Hallucinations, Delusional Thinking, Sensory Disturbances, Stroke, Cerebrovascular Events, Heart Problems, Cardiac Events, Convulsions, Seizures, Muscle Spasms

Summary:

**The Australian Therapeutic Goods Administration released its database of 400 adverse reactions to stimulants in Children taking them. Children as young as five suffered strokes, heart attacks, hallucinations and convulsions.**

Source:

"Dark side of a wonder drug" The Australian, March 28, 2006.

<< Close

Warning ID: 507

Brand Names:

Ritalin, Adderall, Concerta

Generic Names:

Methylphenidate, Amphetamine and Dextroamphetamine

Drug Class:

Stimulant

Ages:

Children (under 18)

Date:

February 9, 2006 Country: United States

Side Effects:

Heart Problems, Cardiac Events, Stroke, Cerebrovascular Events, Death, Sudden Death

Summary:

**The FDA's Drug Safety and Risk Management Advisory Committee urged that the strongest "black box" warning be issued for ADHD stimulants, including Ritalin, Adderall and Concerta because of the risk of heart attacks, strokes and sudden deaths. Dr. Steven Nissen, a cardiologist and member of the advisory committee called this a "potential public health crisis." The FDA said it had received reports of about 25 deaths linked to the drugs and a larger number of cases involving serious consequences, such as heart attacks.**

Source:

"Warning Urged for ADHD Drugs" LATimes.com, February 10, 2006.

<< Close

Warning ID: 495

Brand Names:

Ritalin, Concerta, Metadate

Generic Name:

Methylphenidate

Drug Class:

Stimulant

Ages:

Children (under 18)

Date:

October 1, 1995 Country: United States

Side Effects:

Mania, Psychosis, Aggression, Violence

Summary:

**The U.S. Drug Enforcement Administration (DEA) said methylphenidate use could lead to addiction and that "psychotic episodes, violent behavior and bizarre mannerisms had been reported" with its abuse.**

Source:

"Methylphenidate," U.S. Drug Enforcement Administration (DEA), October 1995.