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<th>Adis RPI Record</th>
<th>Document Name</th>
<th>Drug Name</th>
<th>Release Date</th>
<th>Adverse Event</th>
<th>No of Cases</th>
<th>Serious</th>
<th>First Report</th>
<th>Narrative</th>
<th>Citation</th>
<th>Country</th>
<th>Record Type</th>
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</table>
| 1 803010726     | Rosiglitazone Pancytopenia, myelosuppression and exophthalmos: case report | Rosiglitazone | 10 May 2010 | Exophthalmos Myelosuppression Pancytopenia | 1 | Yes | No | A 60-year-old woman presented with marrow suppressive pancytopenia manifesting as myelodysplastic syndrome (MDS), hypererythropoiesis, and exophthalmos [proptosis] during treatment with rosiglitazone for type 2 diabetes mellitus. The woman, a retired nurse, had been receiving rosiglitazone (Avandia) 4 mg twice daily since 2004. In 2005, a screening complete blood count revealed mild leucopenia and new-onset anaemia. [CONT.]
|                |                |            |              |               |             |         |              |           | Clevidence DE, Juckett MB, Lucarelli MJ. Marrow suppression with myelodysplastic features, hypererythropoiesis, and iopthropic proptosis due to rosiglitazone. Wisconsin Medical Journal 108, 442-5, No. 9, Dec 2009 (English) | USA | Case Report |
| 2 803008021     | Rosiglitazone Diabetic macular oedema: case report | Rosiglitazone | 08 Apr 2010 | Retinal oedema | 1 | No | No | A 61-year-old woman with non-insulin dependent type 2 diabetes mellitus (T2DM) developed diabetic macular oedema during treatment with rosiglitazone. The woman, whose T2DM had been complicated by severe diabetic retinopathy and neuropathy in her legs, was referred for management of worsening bilateral diabetic macular oedema. She had started receiving rosiglitazone 4 mg/day three months before presentation, and her visual impairment appeared to have started with treatment initiations. [CONT.]
| 3 803007921     | Fenofibrate/pioglitazone/rosiglitazone Low HDL cholesterol in an elderly patient: case report | Fenofibrate Pioglitazone Rosiglitazone | 11 Mar 2010 | Low HDL cholesterol | 1 | No | No | A 72-year-old woman with type 2 diabetes mellitus receiving fenofibrate 150mg [Supralip, frequency not stated] in May 2003. Rosiglitazone 4mg [frequency not stated] was added in March 2005. She was also receiving rosuvastatin and metformin. In June 2005, rosiglitazone was increased to 8mg. In June 2006, her HDL-C level was 0.4 mmol/L [time to reaction onset not stated]. Rosuvastatin was reduced, but her HDL-C and ApoA1 levels reached 0.2 mmol/L and 28 mg/dL, respectively. [CONT.]
| 4 803008075     | Pioglitazone/rosiglitazone Liver failure: 17 case reports | Pioglitazone Rosiglitazone | 03 Mar 2010 | Liver failure | 17 | Yes | No | Seventeen patients developed liver failure during treatment with pioglitazone or rosiglitazone [therapeutic indications and times to reaction onset not stated]; these patients were retrospectively identified. Three women and six men, aged 46-73 years, received rosiglitazone 2.8-9 mg/day for 0.2-225 weeks [treatment duration not stated for one patient], and three women and five men, aged 51-82 years, received pioglitazone 15-45 mg/day for 1-26 weeks. [CONT.]
|                |                |            |              |               |             |         |              |           | Floyd JS, Barbehevin E, Lurie P, Wolfe SM. Case series of liver failure associated with rosiglitazone and pioglitazone. Pharmacopsiopharmacology and Drug Safety 18: 1238-43, No. 12, Dec 2009 (English) | USA | Case Report |
| 5 803008074     | Rosiglitazone Anasarca in an elderly patient: case report | Rosiglitazone | 04 Feb 2010 | Oedema Pulmonary oedema | 1 | Yes | No | A 68-year-old woman developed anasarca during treatment with rosiglitazone for type 2 diabetes mellitus. [CONT.]
|                |                |            |              |               |             |         |              |           | Dagdelen S, Kurt M, Aydin K, Bariaklar M. Rosiglitazone-induced anasarca without heart failure: Capillary leakage? Hormones | Turkey | Case Report |
The woman, who had been on insulin therapy for 16 years, started receiving additional rosiglitazone 4mg once daily, increased to twice daily administration after 62 days. On day 97 of rosiglitazone initiation, she was admitted with a 3-week history of progressive dyspnoea, orthopnoea and paroxysmal nocturnal dyspnoea. Community-acquired atypical pneumonia was diagnosed. The woman received clarithromycin and was discharged. [CONT.]

Rosiglitazone Proliferation in an elderly patient: case report
Rosiglitazone
18 Dec 2009
Eye disorders
1
Yes
No
A 67-year-old man developed proptosis during treatment with rosiglitazone for type 2 diabetes mellitus. The man, who also had hypertension, presented with persistent and progressive bilateral oedema of his upper and lower eyelids 2.5 years after starting treatment with rosiglitazone (dosage not stated). He reported that he had had concerns about the progressive lid oedema since starting the agent. His other medications comprised amlodipine/benazepril, metformin and glipizide. [CONT.]


Rosiglitazone Heart failure in an elderly patient: case report
Rosiglitazone
13 Nov 2009
Heart failure
1
Yes
No
A 74-year-old woman, who had no history of heart failure, began therapy with rosiglitazone 4 mg/day, which was increased to 8 mg/day after 1 month. She had previously been treated with gliclazide for her type 2 diabetes mellitus. Within a month, she experienced significant weight gain and subsequently developed heart failure. The woman discontinued treatment with rosiglitazone and her oedema was treated with diuretic therapy [outcome not stated].

Yavasoglu I, Arslan E. Heart failure due to rosiglitazone at older patient. Turk Geriatri Dergisi 11: 140-142, No. 3, 2008 (Turkish)

Rosiglitazone Syndrome of inappropriate antidiuretic hormone secretion (first report) in an elderly patient: case report
Rosiglitazone
26 May 2009
Inappropriate antidiuretic hormone secretion
1
Yes
Yes
An 89-year-old woman developed syndrome of inappropriate antidiuretic hormone secretion (SIADH) during treatment with rosiglitazone. The woman was hospitalised due to a loss of consciousness. She had complained of general weakness over the prior 15 days, plus nausea and vomiting over the prior 3 days. [CONT.]

Berker D, Aydin Y, Arslacu A, Ustun I, Ergun B, Güler S. Severe hyponatraemia due to rosiglitazone use in an elderly woman with diabetes mellitus: a rare cause of syndrome of inappropriate antidiuretic hormone secretion. Endocrine Practice 14: 1017-1019, No. 8, Nov 2008 (English)

Rosiglitazone Acute interstitial nephritis in an elderly patient: case report
Rosiglitazone
20 Apr 2009
Interstitial nephritis
1
Yes
No
A 65-year-old man developed acute interstitial nephritis after starting rosiglitazone for diabetes mellitus. In addition to long-standing diabetes, the man had a broad medical history including hypertension of 15 years' duration, background nephropathy and diabetic nephropathy; his baseline creatinine level had been stable at 130-150 µmol/L. For the past few years. During a clinic visit 2 weeks prior to admission, he complained of bloating with acarbose and reporting omitting some doses. [CONT.]

Abdul Ghani R, Zainudin S, Kamaruddin NA, Kong NCT. Acute renal failure following the use of rosiglitazone in a chronic kidney disease patient. Singapore Medical Journal 50: e32-e34, No. 1, 1 Jan 2009 (English)

Rosiglitazone Volume overload leading to pulmonary hypertension in an elderly patient
Rosiglitazone
19 Mar 2009
Hypervolaemia
1
Yes
No
A 65-year-old diabetic woman developed volume overload leading to pulmonary

Michaelson J. Thiazolidinedione associated volume overload and pulmonary
patient: case report

hypertension (PH) during treatment with rosiglitazone [Avandia]. The woman, who had a history of type 2 diabetes mellitus, obesity, hypertension and aortic stenosis, was receiving rosiglitazone 4mg twice daily plus amiodipine, fexofenadine, furosemide, rabeprazole, glipizide, lisinopril and simvastatin. [CONT.]

hypertension. Therapeutic Advances in Cardiovascular Disease 2: 435-438, No. 6, Dec 2008 (English)

Three patients developed decreased HDL cholesterol levels during concomitant treatment with rosiglitazone [therapeutic indication not clearly stated] and fenofibrate [dosages and duration of treatment before reaction onset not stated]. A 66-year-old woman, who had type 2 diabetes mellitus, lipid metabolism disorders and coronary artery disease, was treated with rosiglitazone, metoprolol, aspirin, metformin, and fluvastatin. Metformin was increased in dosage and fenofibrate was initiated due to hypertriglyceridaemia. [CONT.]


Three patients developed decreased HDL cholesterol levels during concomitant treatment with rosiglitazone [dosages and therapeutic indications not stated]. A 71-year-old woman died from HF and acute respiratory insufficiency. [CONT.]

Lareb. Overview of cardiac adverse drug reactions reported in association with rosiglitazone. Internet Document : [3 pages], 10 Jan 2008. Available from: URL: http://www.larebl.nl (English)
<table>
<thead>
<tr>
<th>Case Report ID</th>
<th>Title</th>
<th>Date</th>
<th>Reactions</th>
<th>Drugs</th>
<th>Therapeutic Indications</th>
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<tbody>
<tr>
<td>16</td>
<td>Rosiglitazone Fluid retention leading to anasarca and congestive heart failure in an elderly patient with hypertension: case report</td>
<td>19 Nov 2007</td>
<td>Congestive heart failure; Oedema</td>
<td>Rosiglitazone</td>
<td>A 77-year-old woman with hypertension; developed fluid retention, and subsequent congestive heart failure, after starting treatment with rosiglitazone for type 2 diabetes mellitus. The woman, who had started receiving rosiglitazone 8 mg/day approximately 36 months previously, was hospitalised with progressive dyspnoea and swelling of her extremities; at this time, she had hypothyroidism, morbid obesity, paroxysmal atrial fibrillation and sciatika, and was receiving metoprolol tartrate, lisinopril, hydrochlorothiazide, furosemide, repaglinide, gabapentin and levothyroxine sodium.</td>
</tr>
<tr>
<td>17</td>
<td>Pioglitazone/rosiglitazone Salivary gland enlargement (first report) in elderly patients: 3 case reports</td>
<td>15 Nov 2007</td>
<td>Salivary gland disorders</td>
<td>Pioglitazone; Rosiglitazone</td>
<td>Three patients developed salivary gland enlargement following the use of pioglitazone (patient 1) and rosiglitazone (patients 2 and 3) (therapeutic indication and dosage not stated). Five weeks after initiating pioglitazone treatment, a 65-year-old man (patient 1) developed parotitis bilaterally. His concomitant medications included acenocoumarol, salmeterol/fluticasone propionate and hydrochlorothiazide. His symptoms subsided after pioglitazone was discontinued.</td>
</tr>
<tr>
<td>18</td>
<td>Rosiglitazone Muscle pain and elevated creatine kinase levels: case report</td>
<td>07 Mar 2007</td>
<td>Elevated creatine kinase levels; Muscle pain</td>
<td>Rosiglitazone</td>
<td>A 42-year-old man developed muscle pain and elevated creatine kinase (CK) levels during treatment with rosiglitazone for type 2 diabetes mellitus. The man started receiving rosiglitazone 8 mg/day. On routine follow-up after 5 months of therapy, it was noted that his CK level was elevated at 555 U/L. Repeat blood tests revealed CK levels of 1125 U/L and 812 U/L after 9 and 19 days, respectively; he also reported muscle pains at this time.</td>
</tr>
<tr>
<td>19</td>
<td>Fibric acid derivatives/rosiglitazone Paradoxical decrease in HDL cholesterol levels: 5 case reports</td>
<td>18 Jan 2007</td>
<td>Low HDL cholesterol</td>
<td>Bezafibrate; Fenofibrate; Rosiglitazone</td>
<td>Five patients with type 2 diabetes mellitus experienced a paradoxical decrease in their HDL cholesterol levels during treatment with a fibric acid derivative and rosiglitazone (therapeutic indications not clearly stated; duration of treatment before reaction onset not stated). In four patients, the fibric acid derivative was fenofibrate; the fifth patient received bezafibrate.</td>
</tr>
<tr>
<td>20</td>
<td>Rosiglitazone Low HDL-cholesterol levels: 2 case reports</td>
<td>07 Nov 2006</td>
<td>Lipid metabolism disorders; Low HDL cholesterol</td>
<td>Rosiglitazone</td>
<td>Two men with lipid metabolism disorders developed low HDL-cholesterol levels during treatment with rosiglitazone for diabetes mellitus; they also experienced increased triglyceride levels. A 47-year-old man, who had a HDL-...</td>
</tr>
</tbody>
</table>
Medical history of a 29-year-old woman who was diagnosed with type 2 diabetes mellitus and started receiving rosiglitazone 4mg every 12 hours, along with aspirin, fenofibrate, pantoprazole, and ascorbic acid (vitamin C) during pregnancy. Baby was born healthy after receiving rosiglitazone and fluoxetine.

**References:***


inhibitors, started rosiglitazone 4mg twice daily. Three months later, he was admitted with a 3-week history of headache. Examination showed bilateral papilloedema without evidence of diabetic and/or hypertensive retinopathy. His fasting plasma glucose level was 8.9 mmol/L, and glycosylated haemoglobin was 7.9%. [CONT.]

A 61-year-old man receiving rosiglitazone for diabetes mellitus developed recurrent pleural effusion after undergoing coronary artery bypass. The man had been receiving rosiglitazone [dosage not stated] for 4 years, along with insulin, valsartan and aspirin, when he underwent coronary artery bypass. He was discharged receiving the same medications. He presented 1 week later with severe dyspnoea, and a chest x-ray revealed a left pleural effusion.

A 31-year-old man with a family history of diabetes mellitus presented with malaise and hyperglycaemia. He received metformin and aspirin initially, and rosiglitazone [Avandia] 4 mg/day was added 2 years later, with the dosage increased to 8 mg/day after 2 weeks. Two months after starting rosiglitazone, laboratory investigations revealed an elevated creatine kinase (CK) level of 746 IU/L; he reported no muscle pain. Rosiglitazone was discontinued and, after 1 month, his CK level had normalised.

A 75-year-old man, who had a history of hypertension, diabetic neuropathy, mild asymptomatic creatine kinase (CK) elevation and hepatic steatosis, developed acute muscular disorders while receiving fenofibrate for hyperlipidaemia and rosiglitazone for diabetes mellitus.

Twelve weeks after switching from simvastatin to fenofibrate 200 mg/day, the man started treatment with rosiglitazone 2mg twice daily. He was hospitalised 23 days later with acute-onset pain and cramps in his calf muscles.

A 50-year-old woman developed leucopenia and thrombocytopenia during sequential treatment with rosiglitazone and pioglitazone for type 2 diabetes mellitus. The woman, who was receiving glipizide, started treatment with rosiglitazone 4 mg/day, with the dosage increased 6 months later to 8 mg/day. After approximately 17 months, she presented with a 2-month history of fatigue and leg cramps.

A 54-year-old woman and 53-year-old man developing leucopenia and thrombocytopenia during sequential treatment with pioglitazone and rosiglitazone for type 2 diabetes mellitus. The woman, who was receiving glipizide, started treatment with rosiglitazone 4 mg/day, with the dosage increased 6 months later to 8 mg/day. After approximately 17 months, she presented with a 2-month history of fatigue and leg cramps.
Rosiglitazone

31 801225338 Rosiglitazone First report of retinal oedema: case report Rosiglitazone 30 Nov 2005 Retinal oedema 1 No Yes A 55-year-old man developed retinal oedema during treatment with rosiglitazone for diabetes mellitus. The man, who had proliferative diabetic retinopathy, nephropathies and neuropathies, and had been receiving rosiglitazone for 3 years, had his rosiglitazone dosage increased from 2 to 8 mg/day. One month later, he noted a vision loss. He experienced an insidious vision decrease in each eye during a 2-week period. Peripheral oedema was also noted after rosiglitazone was increased. [CONT.]

W. Hart, L'I. Spouwen P. ROMIJN JA. Irreversible T2D-induced pubic fat hypertrophy: an embarrassing side-effect. Diabetologia 48 (Suppl. 1): 282, Aug 2005 (English)

32 800975002 Rosiglitazone First report of pancytopenia: case report Rosiglitazone 23 Aug 2005 Pancytopenia 1 No Yes A 56-year-old woman developed pancytopenia during treatment with rosiglitazone for type 2 diabetes mellitus. The woman, who had a history of ischaemic heart disease and hypertension, started treatment with rosiglitazone 4 mg/day [duration of treatment not stated]. Her concomitant medication included aspirin, propranolol, amiodipine, phenoxbenzamine and simvastatin. Initial laboratory investigations revealed a haemoglobin level of 14.4 g/dL, an haematocrit of 49.5%, a WBC count of 4700/mL and a platelet count of 238 000/mL. [CONT.]

Maaravi Y, Stassman J. Mild, reversible pancytopenia induced by rosiglitazone. Diabetes Care 28: 1536, No. 6, Jun 2005 (English)

33 800961675 Rosiglitazone Decreased HDL cholesterol levels: case report Rosiglitazone 08 Jul 2005 Lipid metabolism disorders 1 No No HDL cholesterol levels decreased in a 61-year-old woman receiving rosiglitazone for type 2 diabetes mellitus. The woman, who had been receiving fenofibrate, metformin and glibenclamide for > 1 year and perindopril for 9 months, started treatment with rosiglitazone [Avandia] 8 mg/day, at which time her serum HDL cholesterol level was 1.06 mmol/L. Approximately 3 months later, her HDL cholesterol level had decreased to 0.27 mmol/L. [CONT.]

Willecox D. Rosiglitazone (Avandia): decreased high-density lipoprotein cholesterol levels. Canadian Adverse Reaction Newsletter 15: 2, No. 3, Jul 2005 (English)

34 807219818 Rosiglitazone First report of exophthalmos: case report Rosiglitazone 31 May 2005 Exophthalmos 1 No Yes A 53-year-old woman developed exophthalmos during treatment with rosiglitazone for type 2 diabetes mellitus. The woman, who had a history of globe prominence, presented with a 1-year history of gradually progressive, painless, bilateral exophthalmos 18 months after starting treatment with rosiglitazone 8 mg/day. She also reported recent weight gain, with a 4 inch Levin F, Kazim M, Smith T.J, Marcovici E. Rosiglitazone-induced proptosis. Archives of Ophthalmology 123: 119-121, No. 1, Jan 2005 (English)

Three patients developed severe hypoalphalipoproteinaemia during treatment with rosiglitazone for type 2 diabetes mellitus [see table for details]. Patient 1, who also had a history of mixed hyperlipidaemia, was receiving a sulphonylurea, metformin, a HMG-CoA reductase inhibitor and a bezafibrate. When his glycosylated haemoglobin (HbA1c) was 9%, he started treatment with rosiglitazone 4 mg/day. Four months later, his HDL cholesterol level decreased to 0.31 mmol/L and HbA1c decreased to 6.5%. [CONT.]

Sarker A, Semple RK, Dinnenen SF, O'Rahilly S, Martin SC. Severe hypo-alpha-lipoproteinaemia during treatment with rosiglitazone. Diabetes Care 27: 2577-2580, No. 11, Nov 2004 (English)

Six patients developed oedema and/or congestive heart failure (CHF) during treatment with pioglitazone or rosiglitazone for type 2 diabetes mellitus. The patients were three women (aged 53-64 years) and three men (aged 62-79 years). All of the patients were obese and hypertensive, five had left ventricular hypertrophy, five had diabetes, three had pre-existing coronary heart disease (CHD), one had pre-existing CHF, five had microvascular complications and three were receiving concomitant insulin therapy. [CONT.]


A man, approximately 68-years-old, developed lipomatosis while receiving rosiglitazone for HIV-associated lipoatrophy. The man, who had a history of four to five lipomas as a teenager, started treatment with rosiglitazone [dosage not stated] to increase peripheral fat and increase insulin sensitisation. Over the next 3 months, he developed multiple 1-4cm lipomas on both arms and upper thighs, but did not gain weight. [CONT.]


Two patients developed congestive heart failure during treatment with thiazolidinediones for type 2 diabetes mellitus. The first patient, an obese 57-year-old man with a history of diabetic complications but no symptoms of cardiac disease, had pioglitazone 30 mg/day added to his insulin regimen and, 4 weeks later, he had gained 14kg in weight and noted peripheral oedema. [CONT.]

Cheng AYY, Fantus IG. Thiazolidinedione-induced congestive heart failure. Annals of Pharmacotherapy 38: 817-820, No. 5, May 2004 (English)

A 54-year-old man developed oedema in one leg while receiving rosiglitazone for type 2 diabetes mellitus. The man had a 7-year history of type 2 diabetes for which he had been receiving rosiglitazone 4mg twice daily, insulin glargine, metformin and glimepiride. After 26 months of rosiglitazone treatment he suddenly developed a painful swelling and temperature in his leg. [CONT.]

Bell DSH. Unilateral edema due to a thiazolidinedione. Diabetes Care 26: 2700, No. 9, Sep 2003 (English)

USA
right leg, with pitting oedema to just below his knee but no tenderness. [CONT.]

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**Rosiglitazone Heart failure exacerbation in an elderly patient: case report**

<table>
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<th>Case Number</th>
<th>Date</th>
<th>Event</th>
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<td>Heart failure</td>
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<td>Yes</td>
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<td>41</td>
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<td>Oedema</td>
<td>Rosiglitazone</td>
<td>807211454</td>
<td>Yes</td>
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<td>42</td>
<td>21 Oct 2002</td>
<td>Cholestasis</td>
<td>Rosiglitazone/Troglitazone</td>
<td>800914007</td>
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<td>43</td>
<td>23 Aug 2002</td>
<td>Granulomatosis Hepatitis</td>
<td>Rosiglitazone</td>
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<td>44</td>
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<td>45</td>
<td>18 Feb 2002</td>
<td>Hepatic encephalopathy</td>
<td>Rosiglitazone</td>
<td>800858992</td>
<td>Yes</td>
<td>No</td>
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</table>

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A 74-year-old man with a history of coronary artery disease and heart failure experienced heart failure exacerbation after starting rosiglitazone treatment for type 2 diabetes mellitus. The man, who also had chronic renal insufficiency, started receiving rosiglitazone 4 mg/day, increased after 1 month to 8 mg/day. His existing medications included paracetamol [acetaminophen], aspirin, bumetanide, digoxin, gabapentin, simvastatin, metoprolol and nitroglycerin as needed. [CONT.]

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Kuschel U, Hesselebarth N, Herrmann A, Hiipus M, Hofmann A. Severe electrolyte failure and edemas under therapy with rosiglitazone. Medizinische Klinik 97: 553-555, 15 Sep 2002 (German)

Borkovsky HL, Azer A, Bird S, Szabo G, BANNER B. Severe cholestatic hepatitis caused by thiazolidinediones: risks associated with substituting rosiglitazone for troglitazone. Digestive Diseases and Sciences 47: 1632-1637, Jul 2002 (English)


Niemeyer NV, Janney LM. Thiazolidinedione-induced edema. Pharmacotherapy 22: 924-929, Jul 2002 (English)

Liver failure in a patient treated with long-term rosiglitazone therapy. American Journal of Medicine 111: 584-585, Nov 2001 (English)

An elderly patient developed fatal hepatic encephalopathy during treatment with rosiglitazone. The man had been receiving rosiglitazone (dosage not stated) for more than 1 year when he was admitted to hospital with a 3-week history of nausea, malaise, and general weakness. Investigations revealed mild jaundice and right upper quadrant tenderness. His BP was 190/90mm Hg, his respiration rate was 26 breaths/min, and his heart rate was 100 beats/min.

Rosiglitazone First report of granulomatous hepatitis: case report
Rosiglitazone Liver disorders: case report
Rosiglitazone/troglitazone Pulmonary and peripheral oedema in elderly patients (first report with rosiglitazone): 2 case reports
Rosiglitazone First report of liver disorders: case report

Treatment with rosiglitazone was associated with the development of granulomatous hepatitis in a 37-year-old man with diabetes mellitus. The man had started treatment with rosiglitazone 4 mg/day with the dosage increased to 8 mg/day after 9 months. After 15 months' treatment, he presented with a 5-day history of nausea, vomiting, diarrhoea and fatigue. He had also experienced a decrease in his bodyweight during the previous month. Jaundice and hepatomegaly were evident upon examination. [CONT.]

Dhawan MK, Castillo RA, Agrawal R, Brodmerkel GJ. Rosiglitazone induced granulomatous hepatitis. American Journal of Gastroenterology 96 (Suppl.): 191, Sep 2001 (English)

A 58-year-old woman with chronic diabetes mellitus experienced hepatic injury and jaundice during treatment with rosiglitazone. Rosiglitazone 4 mg/day was added to the woman's treatment regimen of glibenclamide (glyburide), losartan and hydrochlorothiazide, which she had been receiving for >= 1 year. One week later she was admitted to hospital with jaundice; she had an AST level of 5.23 µkat/L, an ALT level of 4183 nkat/L and a peak bilirubin level of 2.4 mg/dl.

Ravivuthala RS, Nori U. Rosiglitazone toxicity. Annals of Internal Medicine 133: 658, 17 Oct 2000 (English)

Two patients developed pulmonary and peripheral oedema during treatment with rosiglitazone and/or troglitazone for type 2 diabetes mellitus. The first patient, a 79-year-old man, also had renal insufficiency, chronic obstructive pulmonary disease, atrial fibrillation, hypertension and congestive heart failure, and he was also receiving verapamil, warfarin, ipratropium bromide and salbutamol (albuterol). He was hospitalised with shortness of breath 6 months after starting treatment with rosiglitazone 8 mg/day. [CONT.]

Thomas ML, Lloyd SJ. Pulmonary oedema associated with rosiglitazone and troglitazone. Annals of Pharmacotherapy 35: 123-124, Jan 2001 (English)

A 61-year-old man experienced liver disorders during treatment with rosiglitazone 4 mg/day for type 2 diabetes mellitus. Two weeks after starting treatment with rosiglitazone, the man presented with anorexia, nausea, vomiting and abdominal pain of 3 days' duration. He also had fatigue, chills and dark urine.


A 58-year-old woman with chronic diabetes mellitus experienced hepatic injury and jaundice during treatment with rosiglitazone and/or troglitazone for type 2 diabetes mellitus. The man had started treatment with rosiglitazone 4 mg/day with the dosage increased to 8 mg/day after 9 months. After 15 months' treatment, he presented with a 5-day history of nausea, vomiting, diarrhoea and fatigue. He had also experienced a decrease in his bodyweight during the previous month. Jaundice and hepatomegaly were evident upon examination. [CONT.]

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A 61-year-old man experienced liver disorders during treatment with rosiglitazone 4 mg/day for type 2 diabetes mellitus. Two weeks after starting treatment with rosiglitazone, the man presented with anorexia, nausea, vomiting and abdominal pain of 3 days' duration. He also had fatigue, chills and dark urine.

His symptoms had started 8 days after the start of rosiglitazone therapy.

A 69-year-old man developed liver failure following treatment with rosiglitazone 4 mg/day for type 2 diabetes mellitus. At the time the man started rosiglitazone, his liver parameters were normal apart from a total bilirubin level of 1.7 mg/dl. He had a history of atrial fibrillation, hypertension, coronary artery disease and congestive heart failure and his medications included pravastatin and verapamil, which he had taken for more than a year. [CONT.]