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**Id** : i.m.0a2c55e1d81af3b4dc4d550d7bbfe257  
**CN** : SQ1ED00165892  
**Date** : Tuesday, February 4, 2003 2:50:00 AM GMT  
**From** : Ou, Connie  
**To** : Leong, Ronald  
**Subject** : RE: re: Re-Challenge of Seroquel  
**Attachments** :  Diabetes (rechallenge).doc  
**Custodians** : Leong, Ronald

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From:  
Ou, Connie

Sent:  
Tuesday, February 04, 2003 7:39 PM

To:  
Leong, Ronald

Subject:  
RE: re: Re-Challenge of Seroquel

Attachments:  
Diabetes (rechallenge).doc

Ron,

There were limited informatin on reports of glucose dysregulation that described a positive re-challenge.

Please see attached.

Connie

-----Original Message-----

From: Leong, Ronald

Sent: Monday, February 03, 2003 6:20 PM

To: Fontana, Patricia

Cc: Ou, Connie

Subject: RE: re: Re-Challenge of Seroquel

Patricia,

I am forwarding your note to Connie Ou, Seroquel Safety Surveillance Product Manager, to see if we have reports of re-challenge, and the outcomes of re-challenges. Connie has been tracking reports of diabetes related adverse events. I don't recall if there are reports of re-challenge.

Since it may take some time to search our database for reports of re-challenge, I have the following thoughts.

First, it has been the company position that there is insufficient evidence for a causal relationship between Seroquel and diabetes or glucose dysregulation. Accordingly, we are trying to learn as much

about these reports as possible. (See fourth paragraph about useful data for us to have.)

Second, we cannot advise the physician to re-challenge or not to re-challenge the patient. It is the physician's benefit risk judgement. If the physician has tried other antipsychotics, and has the best response to Seroquel, he or she may feel that outweighs the risk of diabetes or hyperglycemia. If the patient develops hyperglycemia or diabetes on re-challenge, the physician may decide to continue Seroquel and use standard treatments for diabetes (e.g. diet, oral hypoglycemic drugs, and possibly insulin). Other atypical antipsychotics, particularly olanzapine, have been associated with diabetes, and some studies have even shown an association with the typical antipsychotics. All the anti-psychotic treatments have some risk, diabetes-related and non-diabetes related. The physician needs to balance the benefit with the risk.

If the physician decides to re-challenge the patient, it would be helpful to obtain the following while the patient is not on Seroquel: date Seroquel was discontinued, weight, height, fasting blood glucose, hemoglobin A1c, other medications. The hemoglobin A1c provides a measure of the average glucose level for the preceding 2-3 months. It would helpful to obtain these data after the patient has been on Seroquel, if he or she decides to re-challenge.

I hope this helps.

Regards,

Ron Leong

-----Original Message-----

From: Fontana, Patricia

Sent: Monday, February 03, 2003 5:30 PM

To: Leong, Ronald

Subject: re: Re-Challenge of Seroquel

Hi Ron,

I had a request from a physician who has a patient who developed DM on Seroquel. The Seroquel was subsequently stopped and the blood sugars have seemed to resolve. The doctor would like to re-start SEROQUEL since the patient did well on it and has tried a number of other medications. I have been checking the literature but at this point I have not found anything on re-challenge in this scenario. Do we have any case reports in our databases in this respect or is this really going to be a case of the physician's judgement whether or not to restart the SEROQUEL in this patient? This AE has been reported.

Thanks

Patricia

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